# DISRUPTER SERIES: ADVANCED MATERIALS AND PRODUCTION

### **HEARING**

BEFORE THE

SUBCOMMITTEE ON DIGITAL COMMERCE AND CONSUMER PROTECTION OF THE

# COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES

ONE HUNDRED FIFTEENTH CONGRESS

FIRST SESSION

MARCH 15, 2017

Serial No. 115-11



Printed for the use of the Committee on Energy and Commerce energy commerce. house. gov

U.S. GOVERNMENT PUBLISHING OFFICE

25-297

WASHINGTON: 2018

#### COMMITTEE ON ENERGY AND COMMERCE

#### GREG WALDEN, Oregon Chairman

JOE BARTON, Texas Vice Chairman FRED UPTON, Michigan JOHN SHIMKUS, Illinois TIM MURPHY, Pennsylvania MICHAEL C. BURGESS, Texas MARSHA BLACKBURN, Tennessee STEVE SCALISE, Louisiana
ROBERT E. LATTA, Ohio
CATHY McMORRIS RODGERS, Washington GREGG HARPER, Mississippi GREGG HARPER, Mississippi LEONARD LANCE, New Jersey BRETT GUTHRIE, Kentucky PETE OLSON, Texas DAVID B. McKINLEY, West Virginia ADAM KINZINGER, Illinois H. MORGAN GRIFFITH, Virginia GUS M. BILIRAKIS, Florida BILL JOHNSON, Ohio BILLY LONG, Missouri LARRY BUCSHON, Indiana BILL FLORES. Texas BILL FLORES, Texas SUSAN W. BROOKS, Indiana MARKWAYNE MULLIN, Oklahoma RICHARD HUDSON, North Carolina CHRIS COLLINS, New York KEVIN CRAMER, North Dakota TIM WALBERG, Michigan MIMI WALTERS, California RYAN A. COSTELLO, Pennsylvania EARL L. "BUDDY" CARTER, Georgia

FRANK PALLONE, JR., New Jersey
Ranking Member
BOBBY L. RUSH, Illinois
ANNA G. ESHOO, California
ELIOT L. ENGEL, New York
GENE GREEN, Texas
DIANA DEGETTE, Colorado
MICHAEL F. DOYLE, Pennsylvania
JANICE D. SCHAKOWSKY, Illinois
G.K. BUTTERFIELD, North Carolina
DORIS O. MATSUI, California
KATHY CASTOR, Florida
JOHN P. SARBANES, Maryland
JERRY MCNERNEY, California
PETER WELCH, Vermont
BEN RAY LUJAN, New Mexico
PAUL TONKO, New York
YVETTE D. CLARKE, New York
DAVID LOEBSACK, Iowa
KURT SCHRADER, Oregon
JOSEPH P. KENNEDY, III, Massachusetts
TONY CARDENAS, California
RAUL RUIZ, California
SCOTT H. PETERS, California
DEBBIE DINGELL, Michigan

#### SUBCOMMITTEE ON DIGITAL COMMERCE AND CONSUMER PROTECTION

### ROBERT E. LATTA, Ohio Chairman

GREGG HARPER, Mississippi Vice Chairman
FRED UPTON, Michigan
MICHAEL C. BURGESS, Texas
LEONARD LANCE, New Jersey
BRETT GUTHRIE, Kentucky
DAVID B. McKINLEY, West Virgina
ADAM KINZINGER, Illinois
GUS M. BILIRAKIS, Florida
LARRY BUCSHON, Indiana
MARKWAYNE MULLIN, Oklahoma
MIMI WALTERS, California
RYAN A. COSTELLO, Pennsylvania
GREG WALDEN, Oregon (ex officio)

JANICE D. SCHAKOWSKY, Illinois Ranking Member
BEN RAY LUJÁN, New Mexico
YVETTE D. CLARKE, New York
TONY CARDENAS, California
DEBBIE DINGELL, Michigan
DORIS O. MATSUI, California
PETER WELCH, Vermont
JOSEPH P. KENNEDY, III, Massachusetts
GENE GREEN, Texas
FRANK PALLONE, JR., New Jersey (ex
officio)

### CONTENTS

	Page
Hon. Robert E. Latta, a Representative in Congress from the State of Ohio, opening statement	1 2
Hon. Doris O. Matsui, a Representative in Congress from the State of California, opening statement	4
Hon. Greg Walden, a Representative in Congress from the State of Oregon, opening statement	5
Prepared statement  Hon. Frank Pallone, Jr., a Representative in Congress from the State of	6
New Jersey, prepared statement	7
WITNESSES	
James M. Tour, W.F. Chao Professor of Chemistry, Professor of Computer Science, and Professor of Materials Science and Nanoengineering, Smalley Institute for Nanoscale Science & Technology, Rice University  Prepared statement  Keith Murphy, Chairman and Chief Executive Officer, Organovo Holdings, Inc.	9 11 20
Prepared statement  Afsaneh Rabiei, Professor, Department of Mechanical and Aerospace Engineering, North Carolina State University  Prepared statement	22 29 31
Hota Gangarao, Maurice A. and Jo Ann Wadsworth Distinguished Professor of CEE, CEMR, Director, Constructed Facilities Center, West Virginia University	36
Prepared statement Shane E. Weyant, Chief Executive Officer And President, Creative Pultrusions, Inc. Prepared statement	38 48 50

#### DISRUPTER SERIES: ADVANCED MATERIALS AND PRODUCTION

#### WEDNESDAY, MARCH 15, 2017

House of Representatives, SUBCOMMITTEE ON DIGITAL COMMERCE AND CONSUMER PROTECTION, COMMITTEE ON ENERGY AND COMMERCE, Washington, DC.

The subcommittee met, pursuant to call, at 1:03 p.m., in room 2322, Rayburn House Office Building, Hon. Robert Latta, (chairman of the subcommittee) presiding.

Present: Representatives Latta, Harper, Burgess, Lance, Guthrie, McKinley, Kinzinger, Mullin, Walters, Costello, Walden (ex officio), Schakowsky, Matsui, Kennedy, and Pallone (ex officio).

Staff Present: Blair Ellis, Digital Coordinator Press Secretary; Melissa Froelich, Counsel, Digital Commerce and Consumer Protection; Giulia Giannangeli Legislative Clerk, Digital Commerce and Consumer Protection/Environment; Alex Miller, Video Production Aide and Press Assistant; Paul Nagle, Chief Counsel, Digital Commerce and Consumer Protection, Olivia Trusty, Professional Staff Member, Digital Commerce and Consumer Protection; Madeline Vey, Policy Coordinator, Digital Commerce and Consumer Protection; Hamlin Wade, Special Advisor, External Affairs, Everett Winnick, Director of Information Technology; Michelle Ash, Minority Chief Counsel, Digital Commerce and Consumer Protection; Jeff Carroll, Minority Staff Director; Lisa Goldman, Minority Counsel; Caroline Paris-Behr, Minority Policy Analyst; Andrew Souvall, Minority Director of Communications, Outreach and Member Services; and C.J. Young, Minority Press Secretary.

#### OPENING STATEMENT OF HON. ROBERT E. LATTA, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO

Mr. LATTA. The Subcommittee on Digital Commerce and Consumer Protection will now come to order; and the chair recognizes himself for 5 minutes for an opening statement.

And pardon me, I get down here after about 12 hours, and my

allergies already start kicking in, even with the snow.

And I also need to just let the witnesses know that we also have the Energy and Commerce's Subcommittee on Energy is meeting right now or in the next 15 minutes. You are going to have members coming in and out, because both subcommittees are meeting at the same time.

But again, good afternoon and welcome to the first hearing of the Disrupter Series in the 115th Congress. I would like to thank all

of our witnesses for their flexibility with the time change, given the weather challenges of the past 2 days. The continuation of the Disrupter Series ensures that the Digital Commerce and Consumer Protection Subcommittee continues to learn about the cutting-edge

developments across industry.

I am excited to continue this series. As chairman, I look forward to more hearings, including tomorrow's hearing on smart communities. Today, we are focused on advanced materials and production methods. The panel of witnesses are experts in a number of different fields, from graphene and other nanoparticles to bio-ink and techniques to 3D print human tissue. We also have experts in new materials and fabrication methods, developing plastics, metals, and composite materials.

The potential for each of these materials, and even those that may not be represented on the panel today, are subject to the health of the U.S. economy and the willingness of public and pri-

vate investors to take some of the amount of the risk.

The applications of these materials is seemingly endless: infrastructure, energy, telecommunication, automobiles, health care,

aerospace, transportation, and more.

The path to future applications and investment in early-stage development can be uncertain, given immediate capital investment requirements. However, on the other end of the equation is the potential for the improved safety and long-term cost savings. There should be a full vetting of the costs and benefits as we examine potential use cases for the advanced materials.

Moreover, if we are serious about improving safety, bringing consumers more and better options, and ensuring manufacturing jobs with that Made in America label, then we must be leaders in the

development and application of these materials.

Basic research and development of new materials often is a result of an accidental discovery or an unexpected result. There is a tumultuous path for many materials from discovery to commercialization. U.S. job growth and material science and engineering is dependent on the health of individual industries over the next 5 to 10 years.

I look forward to hearing from our witnesses about their experiences along this development chain and how the government, at any level, is either helping or hindering further development of the U.S. innovation in material science and advanced production meth-

ods.

[The prepared statement of Mr. Latta follows:]

#### PREPARED STATEMENT OF HON. ROBERT E. LATTA

Good afternoon and welcome to the first hearing of the Disrupter Series in the 115th Congress. I would like to thank all of the witnesses for their flexibility with time change given all of the weather challenges over the last two days. The continuation of the Disrupter Series ensures that the Digital Commerce and Consumer Protection Subcommittee continues to learn about the cutting-edge developments across industries. I am excited to continue this series as Chairman and I look forward to more hearings, including tomorrow's hearing on Smart Communities.

Today we are focused on advanced materials and production methods. The panel of witnesses are experts in a number of different fields from graphene and other nanoparticles to bio-ink and techniques to 3D print human tissue. We also have experts in new materials and fabrication methods developing plastics, metals, and composite materials. The potential for each of these materials, and even those that

may not be represented on the panel today, are subject to the health of the U.S. economy and the willingness of public and private investors to take on some amount

The applications for these materials is seemingly endless: infrastructure, energy, telecommunications, automobiles, health care, aerospace, transportation, and more. The path to future applications, and investment in early stage development, can be uncertain given immediate capital investment requirements. However, on the other end of the equation is the potential for improved safety and long-term cost savings. There should be a full vetting of the costs and benefits as we examine potential use cases for advanced materials.

Moreover, if we are serious about improving safety, bringing consumers more and better options and ensuring manufacturing jobs here in America then we must be leaders in the development and application of these materials.

Basic research and development of new materials often is a result of an accidental discovery or an unexpected result. There is a tumultuous path for many materials from discovery to commercialization. U.S. job growth in materials science and engineering is dependent on the health of individual industries over the next 5-10 years.

I look forward to hearing from the witnesses' about their experiences along this development chain and how the government—at any level—is either helping or hindering further development of U.S. innovation in materials science and advanced production methods.

Mr. LATTA. And I think I have a little bit of time left, and any members on our side that would like to make an opening statement? Mr. McKinley.

Mr. McKinley. Thank you, Mr. Chairman, and good afternoon. I would like to welcome everyone to today's important hearing on advanced materials and production. We are excited about this panel on this topic to learn more about some of the latest developments in material sciences and how they have the potential to revolutionize our industries and electronics and health care.

But I am particularly interested in learning more about the development and commercial applications of graphene. To the rest of the committee, that is a fascinating material that is one atom thick. It is the thinnest material made by man, lightweight, transparent, and 200 times the strength of steel, and holds great promise. Not only that, but also is a semiconductor and in composite construction.

So additionally, I would like to extend a special welcome to one of our witnesses, Dr. Hota GangaRao, with whom, actually professionally, we have worked together on some projects. He is from West Virginia University in Morgantown. And Dr. GangaRao is a Maurice and Jo Ann Wadsworth Distinguished Professor of Civil and Environmental Engineering at WVU, and has done extensive research on the use of composite materials in infrastructure projects.

Dr. GangaRao, I thank you for traveling here today. I ran through that storm yesterday for 5 hours in the snow, and I saw four or five cars over in the ditch. So hopefully, you didn't have the

same experience that I had coming over yesterday.

So, for the rest of you, we look forward to thoughtful discussion with each of you. And I apologize, because I am going to be one, I am in that other committee. I am going to be back and forth here on this, but I want to get back and learn more about this.

So I yield back the balance of my time.

Mr. Latta. Thank you very much. The gentleman yields back. And at this time, the chair would now recognize the gentlelady from California for opening remarks.

## OPENING STATEMENT OF HON. DORIS O. MATSUI, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Ms. Matsui. Thank you very much, Chairman Latta, and I am here instead of the Ranking Member Schakowsky, who is trying to get out of Chicago. So I think you will understand that.

I am glad that some of us are here today, and thank you all for the witnesses for your flexibility on our scheduling. We can't con-

trol the weather, as you know.

This hearing continues the subcommittee's Disrupter Series, where we look at innovative products and technologies. Today, we are looking at advanced materials. Our research institutions have been driving this innovation forward. For instance, the University of California's 10 campuses are doing some of the most cutting-edge research in the world. They regularly lead all universities in the number of patents filed each year. The university's materials research has been pivotal in many fields, but the work being done at UC Davis is particularly impressive. UC Davis engineers have been using 3D printing technology to create personalized, medically accurate models of organs. These models help surgeons determine the best approach for operating on a patient, or whether an operation would be helpful at all.

Researchers at ÛC Davis have also developed technology that integrates renewable organic materials into water bottles. Currently, a plant in my district makes bottles that are 80 percent renewable, and they have a 100 percent renewable goal in sight. These advanced materials and many more being developed and already in use could make it much easier for us to reach environmental and

sustainability goals.

Manufacturers can already use an aluminum-steel alloy that is lighter and stronger than conventional steel. That could mean lighter cars that require less energy. Permeable concrete could reduce flooding and help remove contaminants in groundwater. Our witnesses have many other examples of the ways that composite materials can benefit our communities. The possibilities are exciting; the question is how we get there. Many of these materials were developed through Federal research dollars.

Professor Rabiei lists in a written testimony the many funding sources her team used to develop composite metal foam, which include the National Science Foundation, NASA, the Department of Energy, and the Department of Transportation. Those agencies' funds largely come from nonDefense discretionary appropriations, and today, those funds are at risk. The President has suggested cutting nonDefense discretionary spending by \$54 billion in fiscal year 2018. That is not just cutting excess spending; these cuts could jeopardize our national competitiveness.

This would impair our ability to invest in the country's economic future. It would leave our researchers underfunded, and allow other countries to claim global leadership, instead of encouraging homegrown innovation. If we want continued innovation, we need to invest in the research that makes it happen. That starts with protecting non-Defense discretionary spending in this year's budg-

et.

I look forward to hearing more from our witnesses about how federally funded research has supported development of advanced materials. I am also interested in the challenges of moving from research to market.

Thank you all for being here, and I look forward to your testimony.

And I yield back.

Mr. LATTA. Thank you very much. The gentlelady yields back.

The chair now recognizes the chairman of the full committee, the gentleman from Oregon, for 5 minutes.

#### OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENT-ATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. WALDEN. Thank you very much, Mr. Chairman.

I want to welcome our witnesses and I really appreciate your tes-

timony, which I have enjoyed reading through.

Thank you. Again, thank you for what you are doing. This sub-committee is really, really important in the work of the Energy and Commerce Committee. It gets labeled as a Disrupter Subcommittee in the sense that with all these new technologies and innovations in the private sector, and the partnerships with the public education institutions and all, there are some amazing things we are standing on the cusp of. And so we have held several hearings over the last few years on emerging technologies and as part of the Disrupter Series, from the internet of things and health apps to drones and robotics, revolutionary capabilities with 3D printing. Many of these technologies are literally transforming commerce and creating new opportunities for economic prosperity for Americans and for generations to come.

Today, our Disrupter Series continues with a look at innovative materials and production methods that are the building blocks for some of the emerging technologies that could change how we see

the world.

The work that is taking place at our universities around the country, truly groundbreaking. Today is an opportunity to learn firsthand from you, the top minds in academia. We want to learn about your full spectrum of work, and how basic research and how you shepherd this through your projects to commercialization. As my friend from West Virginia talked about with graphene, hailed as this discovery that will do for the internet of things what silicon did for the chip industry. We have not reached the point of mass commercialization, I understand, but there have been advances in patenting and licensing, and these are really important discoveries for some applications.

Additionally, composite materials incorporating graphene have increased strength and conductivity properties that are not found in more traditional materials. These composites could have interesting applications in the automotive and infrastructure space. So I look forward to hearing from Dr. Tour about his work on

graphene and the U.S.' position relative to other nations.

There is also the opportunity to work with traditional materials to create new composites that could solve some of the competing cost and safety questions. For example, new bridges and car bumpers could both benefit from taking into consideration new tech-

nologies.

So I am interested in hearing from our panelists in industry and academia about their experience approaching investors and clients about their products and services. So, as we look at the relationship between job creation and our Nation's infrastructure, it is crucial we understand the marketplace and what is currently under development.

Remember, simply because a material is new does not mean that it is a realistic replacement for some traditional material. However, there may be improved safety benefits and long-term repair and replacement cost savings in some cases. These are all worthwhile considerations for stakeholders to consider and important factors

that we look forward to hearing from you all today on.

I will admit up front, I have to go down to the Energy Subcommittee and give an opening statement there and hope to bounce back and forth, but I do have your testimony here. And you are in able hands with our terrific chairman of the Subcommittee on Digital Commerce and Consumer Protection, DCCP, which is not a Russian acronym. It may look like that, but it is not.

And with that, I yield back, Mr. Chairman. [The prepared statement of Mr. Walden follows:]

#### PREPARED STATEMENT OF HON. GREG WALDEN

In the last Congress, this subcommittee examined several emerging technologies that are creating new opportunities for economic growth, job creation, and increasing consumer choice in today's increasingly digital world. From the Internet of Things and health apps, to drones and robotics, and the revolutionary capabilities of 3D printing, many of these technologies are transforming commerce and creating new opportunities for economic prosperity in America for generations to come.

Today our Disrupter Series continues with a look at innovative materials and production methods that are the building blocks for some of the emerging technologies that could change how we see the world. The work that is taking place at universities around the country is truly groundbreaking and today is an opportunity to learn first-hand from some of our top minds in academia. I look forward to hearing about the full spectrum of their work—from basic research to how they shepherd their projects through to commercialization.

For example, graphene is hailed as a discovery that will do for the Internet of Things what silicon did for the chip industry. We have not reached the point of mass commercialization yet; however, there have been advancements in patenting and li-

censing these discoveries for some applications.

Additionally, composite materials incorporating graphene have increased strength and conductivity properties that are not found in more traditional materials. These composites could have interesting applications in the automotive and infrastructure space. I look forward to hearing more from Dr. Tour about his work on graphene and the U.S.'s position relative to other nations.

There is also the opportunity to work with traditional materials and create new composites that could solve some of the competing cost and safety questions. For example, new bridges and car bumpers could both benefit from taking into consideration new technologies. I am interested in hearing from our panelists in industry and academia about their experience approaching investors and clients about their

products and services.

As we look at the relationship between job creation and our nation's infrastructure it is critical that we understand the marketplace and what is currently in development. Remember, simply because a material is new does not mean that it is a realistic replacement for more traditional materials. However, there may be improved safety benefits and long-term repair and replacement cost savings in some cases. These are all worthwhile considerations for stakeholders to consider and important factors I look forward to discussing today.

I am pleased that the Disrupter Series is continuing this Congress, and I look forward to hearing from today's witnesses. Thank you for being here.

Mr. LATTA. Thank you very much, Mr. Chairman. And, as I mentioned, we do have members that will be coming in and out.

But at this time, the chair recognizes the gentleman from New Jersey, the ranking member, for his opening statement of 5 minutes.

### OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Mr. Chairman.

Today's hearing gives us the opportunity to explore some ways in which science and scientific research is allowing us to improve materials already in use or create new materials that are more

adaptable to the needs of consumers and industry.

Advanced materials can be found in almost every industry sector. In the aerospace field, a new material composed of a multilayer lamination of glass and plastic is being used in helicopters and planes to make stronger and more durable windshields. Advanced materials research is also happening with regard to a wide range of consumer products.

As one example, researchers are working on creating batteries that are more stable and safer than the common Lithium ion batteries used in so many consumer electronics. Just this week in a tragic accident in Harrisburg, Pennsylvania, a toddler died as a result of an exploding hoverboard. Safer batteries would prevent these kinds of tragedies from occurring.

And today, we are fortunate to have Professor Rabiei—I hope I pronounced it properly—who is here to describe how advanced materials are used to create protective armor, armor that has been described as metal bubble wrap. This metal wrap can be used to protect individuals as well as to protect multiple personnel in vehicles and other forms of transportation.

Now, some of these successes in advanced materials resulted, in part, from the Federal Government's investment in basic scientific research. As with all new scientific breakthroughs, funding for research and development is paramount, and the Federal Government is the largest financial supporter of basic research. The return on publicly funded scientific research and development, R&D, is well-established, and Federal support of this kind of innovation is a key to the success of America's economy.

In 2011, President Obama established the Materials Genome Initiative, that has invested more than \$500 million in Federal funding to discover and deploy advanced materials. President Obama also established the National Network for Manufacturing Innovation, a network of nine federally supported advanced manufac-

turing research institutes throughout the country.

These institutes have provided research centers to academia, industry, and government for testing as well as opportunities to collaborate with others in their fields, or complementary fields of expertise. These institutes work on lightweighting vehicles so that they are more energy-efficient, but still just as strong and safe. They are also promoting 3D printing and manufacturing, develop the fabrics of tomorrow that will act as connected devices, and help

commercialize advanced resin and fiber composites that have a longer room temperature shelf life.

So America's leadership in advanced materials and other important R&D may be at risk, based on the preliminary budget summaries we have seen from the Trump administration. We should not walk away from the significant efforts made or the public funds that have made these advances possible. The U.S. should be the most attractive place to research, develop, commercialize, and produce advanced materials. These are some of the jobs of the future, and we should do everything we can to continue to support this important R&D work so that these jobs stay here in the United States rather than go abroad.

So I am pleased that the subcommittee will have the opportunity today to learn more about advanced materials from those who know it best, the panel. Science, engineering, and technology are together creating jobs, good jobs for Americans, and I hope to see that continue.

But, again, I have to apologize, because I am going to run to the other committee and then come back as well. So I may miss some or all of your testimony. But thank you all for being here.

And I yield back, Mr. Chairman.

Mr. LATTA. Well, thank you very much. The gentleman yields back.

And, again, I want to thank the witnesses for being with us today. And, again, I apologize. We have members that will be back and forth throughout the hearing upstairs and downstairs here.

But, again, I want to, again, thank today's witnesses, and witnesses will have the opportunity to give opening statements, followed by a round of questions from the members.

On our witness panel for today's hearing will include, and I would like to just go through. I know the gentleman from West Vir-

ginia has already given one, but I will give it again.

Dr. James M. Tour, T.T. and W.F. Chao Professor of Chemistry, Computer Science, Material Science, and Nanoengineering, at the Smalley Institute of Nanoscale Science and Technology at Rice University; Mr. Keith Murphy, Chairman and Chief Executive Officer at Organovo Holdings, Inc.; Dr. Afsaneh Rabiei, Professor of Mechanical and Aerospace Engineering at North Carolina State University; Dr. Hota GangaRao, Maurice A. and Jo Ann Wadsworth Distinguished Professor of Civil and Environmental Engineering, Director of Constructed Facilities Center, and Director of Center for Integration of Composites into Infrastructure at West Virginia University; and Mr. Shane Weyant, who is the Chief Executive Officer and President at Creative Pultrusions, Inc.

We appreciate you all being here today, and we are going to begin the panel with Dr. Tour. And you are now recognized for 5 minutes for your opening statements. And, again, thank you very much for being with us.

STATEMENTS OF DR. JAMES M. TOUR, W.F. CHAO PROFESSOR OF CHEMISTRY, PROFESSOR OF COMPUTER SCIENCE, AND PROFESSOR  $\mathbf{OF}$ MATERIALS SCIENCE AND ENGINEERING, SMALLEY INSTITUTE FOR NANOSCALE SCIENCE & TECHNOLOGY, RICE UNIVERSITY; KEITH MUR-CHIEF EXECUTIVE CHAIRMAN AND ORGANOVO HOLDINGS INC.; DR. AFSANEH RABIEI, PRO-FESSOR, DEPARTMENT OF MECHANICAL AND AEROSPACE ENGINEERING, NORTH CAROLINA STATE UNIVERSITY; HOTA GANGARAO, MAURICE A. AND JO ANN WADSWORTH DISTIN-GUISHED PROFESSOR OF CEE, CEMR, DIRECTOR, CONSTRUCTED FACILITIES CENTER, WEST VIRGINIA UNIVER-SITY; AND SHANE WEYANT, CHIEF EXECUTIVE OFFICER AND PRESIDENT, CREATIVE PULTRUSIONS, INC.

#### STATEMENT OF DR. JAMES M. TOUR

Mr. Tour. Thank you. I am here to discuss graphene and establishing U.S. preeminence in the field of this disruptive advanced material. What is graphene? It is a sheet of graphite, one atom thick. At the atomic scale, it looks like chicken wire. I am a professor of chemistry, material science, and nanoengineering at Rice University. I have 625 research publications, 155 of those being on the topic of graphene. I also have 112 patents on graphene, ranking me as the third most prolific graphene inventor in the world and number one in the U.S. Our research on graphene has led to the formation of five nanomaterials and nanomedicine companies, plus suites of licenses to existing large multinational companies.

The U.S. is no longer leading in graphene research and has already lost in graphene production capabilities. Without investment to leverage the private sector, we will cede this advanced material to foreign competitors. At its size scale, graphene is tops for toughness, heat conduction, electrical mobility, and lightweight. From a safety standpoint, we have shown graphene to be nontoxic and environmentally friendly in many respects. A nanomaterial cannot merely be sprinkled like pixie dust into a composite or device to show beneficial behavior, but with persistence and investment, the advances can be realized.

The number of graphene patents rose rapidly during the last 5 years. In 2015, it surpassed the cumulative patent pool of 10 related main groups of technologies. That means that the country that dominates in graphene will dominate in high-technology advances for decades to come. It is now like a space race. China has 25 percent more graphene patents than does the U.S. Of the top 20 entities in the world that hold graphene patents, eight are foreign-owned companies versus three U.S. companies. Eight are foreign universities, all in Asia, while only one U.S. university is on that list, namely, Rice University.

The worldwide market for graphene is a few tens of millions of dollars per year, but now rapidly rising. Bulk-scale production of graphene is an initial part of those revenues, but that is not where the most value resides. The greatest value is from ownership of the innovative techniques to apply graphene in advanced applications that were formerly unforeseen, like in ultrahigh-frequency supercapacitors, or medical device formulations that regenerate damaged

spinal cords within a few weeks to near perfect function. These are two technologies that we have witnessed in our own laboratory.

The country with the best researchers and the easiest route to entrepreneurial success will be preeminent. But the U.S. universities are trailing way behind Asian universities in high-tech equipment for nano-analysis and basic research. This is the result of diminished Federal support for academic science.

Grimmer, however, has been the dramatic loss of our top young investigators from pursuing academic positions, due to the diminished research funds to universities on a per-researcher basis. Our top international students, who formerly always remained in the U.S. to become professors, are returning to their home countries upon graduation, taking our advanced technology expertise with them. Even more frightening, some of our top U.S. established senior professors are moving abroad in order to keep their programs funded. Foreign universities are trolling in the U.S. academies for our top professors. Previously, the U.S. was the recipient of the world's most talented, profiting from the brain drain of other nations. Now, the U.S. is being drained. Sadly, it will take decades to recover from what we have already lost.

I have three recommendations to correct these problems and ensure that the United States is preeminent in graphene advanced materials:

First, Congress should consider the rapid initiation of a \$200 million-per-year program administered over 4 years through the standard Federal science funding agencies, and \$7 million-per-year multi-investigator programs, requiring strong in-kind university and corporate partner matching, and dedicated facilities, equipment, and personnel. That way, the Federal money will be leveraged to produce 50 percent more from university development campaigns, and industrial partners. Programs like the NSF's Innovation Corps could assist in the translation of technology to industry. This is shovel-ready science, and should be thought of in the same way that Congress is addressing infrastructure investment.

Second, we must keep our start-up companies in the U.S. My last three companies were started abroad, but if the U.S. corporate tax rate were reduced to 15 percent, we would gladly remain in the U.S.

Finally, streamline the Green Card process for scientists and engineers that received their Ph.D.s in the U.S. We need them.

In closing, Asia is leading in graphene research and commerce, but I think the U.S. could pull ahead with a little help from the Federal Government. If our congressional leaders would do that, we would beat the pants off our foreign counterparts.

[The prepared statement of Mr. Tour follows:]

# GRAPHENE AND ESTABLISHING U.S. PREEMINENCE IN THE FIELD WRITTEN SUBMISSION

Testimony before the Subcommittee on Digital Commerce and Consumer Protection, United

States House of Representatives

March 15, 2017

James M. Tour, Ph.D.

The NanoCarbon Center, Department of Chemistry, Department of Materials Science and

Nanoengineering, Department of Computer Science

Rice University, Houston Texas

Chairman Latta, Vice Chairman Harper, Ranking Member Schakowsky and other committee members, I appreciate the opportunity to testify before the subcommittee. I am the T.T and W.F. Chao Professor of Chemistry, Professor of Computer Science and Professor of Materials Science and NanoEngineering in the NanoCarbon Center at Rice University in Houston, Texas.

Today we are here to discuss the topic of graphene. Graphene is a single-atom-thick sheet of graphite, ordered in an array of carbon atoms with a repeated hexagonal pattern. Think chickenwire! That's what it looks like, chicken-wire, in its atomic arrangement, but on the one-atom-thick scale.

I am fortunate to personally have 625 research publications with 153 of those being on the topic of graphene. I have 41 US plus 71 international patents or pending patents specifically on the topic of graphene, ranking me as the third most prolific graphene inventor in the world. Our research on graphene has led to the formation of several nanomaterials companies for advanced composites, numerous patent suites being licensed to existing medium and large multinational companies for the manufacture and sale of graphene in electrical energy storage devices, more efficient oil and gas extraction methods, and water purification system. Our work has further led to the formation of two graphene-based nanomedicine companies for treatment of traumatic brain injury (the number one disabler of young adults), stroke (the number one disabler of older adults), and autoimmune diseases such as rheumatoid arthritis and multiple sclerosis.

At its size scale, graphene has many superlatives to its name including highest strength which is good for composites, highest mobility which means the high information transfer rate in electronic devices, the highest heat transfer rate which means that it is good at pulling excess

heat of computers or machines, and the most efficient gas barriers, which means no molecules can pass through it.

But none of this comes easily when trying to apply it to a product that someone will buy. It is a misconception that a nanomaterial can merely be sprinkled like pixy-dust into a composite or device to show beneficial behavior. The transition from the laboratory to a sellable product is a huge hurdle. But again, with persistence and investment, it can be done.

Finally, from an environmental standpoint, we have shown graphene to be environmentally friendly in many respects. The oxidized forms of graphene, graphene oxide, either decomposes in water to form humic acid, which is dirt, or it is converted by safe earth-abundant reducing-bacteria to afford graphene. Graphene then agglomerates back to graphite, a naturally occurring nontoxic mineral found in products like pencils.

The worldwide market for graphene remains small; it's presently just a cottage industry. Some suggest the worldwide market a few tens of millions of dollars, but I suspect it is presently even less than that. However, its potential is enormous and it will soon capture far greater markets.

#### There are three topics relevant to my testimony today:

- 1. The position of the United States as it pertains to basic graphene research and patents.
- 2. The transition of graphene to the marketplace so as to capture optimal value.
- Vaulting the US to preeminence in graphene research that leads to patentable advances.

14

1. The position of the United States as it pertains to basic graphene research and patents.2

Patenting, meaning securing the long-term monetary value of this new material, has taken place at a furious pace. Uses in advanced materials is the number one patent-projected use of graphene, with chemical applications being 60% and electronics being 30% of that advanced materials market. The number of graphene patents rose exponentially during the last years 5 years. In 2015 it surpassed the cumulative patent pool of ten related main groups of technologies.

The potential monetary value of graphene intellectual property (namely patents) was greater than that of the other 10 <u>combined</u> related technology groups, when calculated based on text analytics and the number of forward citations a patent has received. That means that the country that dominates in graphene will dominate in high technology advances for decades to come. It's now a space-race!

The approximate number of patents per country is as follows:

China 8000

US 6000

Korea 4000

Japan 2000

Taiwan 1000

Europe (mainly Germany, the UK and France combined total) 1000

Of the top 20 entities that hold graphene patents in the world:

4

8 are foreign-owned companies (Samsung being the most prolific) vs. only 3 US companies (IBM, Baker Hughes and Lockheed-Martin)

8 are foreign universities (all in Asia, mainly Korea and China) while only 1 US university (Rice University) is in the top-twenty list. Things don't look so good for US industry or US universities on a per institution basis. Samsung (at 637) alone owns almost as many graphene patents as IBM, Baker Hughes and Lockheed-Martin combined (at 736).

Therefore, although the US at 6000 patents trails only China's 8000 patents, the US holdings are more diffuse and there are few graphene patent powerhouses in the US. In direct numbers regarding industrial strength and academic strength, as related to capturing the monetary value, the US is not doing well against Asia. Quality academic publications remains high in the US, but securing intellectual property remains low relative to China and Korea. Thankfully, the US remains far ahead of Europe.

#### 2. The transition of graphene to the marketplace so as to capture optimal value.

Though graphene has extraordinary attributes, none of this is easily captured in scaling to bulk materials. Large-scale production is still hard. Further, in order to have graphene enhance a bulk material two things must be solved for each target application: good dispersion and good interfacial interaction between the nanomaterial and the host material. And all this has to be done while maintaining low enough cost to justify the enhanced performance. This is hard to achieve, but it can be done. For electronics grade graphene, meaning growing graphene as a layer on a metal substrate or by laser writing on polyimide plastic, there are great prospects, but target selection is essential to ensure value and performance in light of the costs.

There is a need for production in bulk for the lower skilled manufacturing jobs in this burgeoning industry, but competition with Asia in this has proven to me hard in the past. But the greatest value comes by being closest to the final customer. The bulk chemical producers' margins are usually thin, and the monetary value winners will not be the bulk graphene suppliers. As an analogy, DuPont's profit margins are much smaller than Apple's margins. Getting closest to the final customer can bring the greatest value. Incorporation of graphene into the final customer products, like smart phone displays and high capacity battery electrodes, will afford the greatest value

#### 3. Vaulting the US to preeminence in graphene research that leads to patentable advances.

The country with the best researchers and the easiest route to entrepreneurial success will succeed. US universities are way behind Asian universities in high tech equipment for nanoanalysis. Asia has built enormous graphene research facilities with the world's best equipment. At Rice, I often collaborate with researchers in Asia, not for their talent, but to secure access to their equipment. In the past 8 years, the lack of funds for research equipment has severely hampered US access to new and updated facilities.

Grimmer, however, has been the dramatic loss of research funding to U.S. universities, on a per investigator basis, since the outpouring of the stimulus funds in 2009 which came so quickly that no rational spending could be manifest. The situation has become untenable. Not only are our best and brightest international students returning to their home countries upon graduation, taking our advanced technology expertise with them, but our top professors also are moving abroad in order to keep their programs funded. For the past century or more, the U.S. had been

the recipient of the world's most talented students, profiting from the brain drain of other nations.

Not so anymore. We are losing our best and brightest.

In 2011 and 2014 to congressional subcommittees, saying that if funding of US research did not increase, the United States would experience a brain drain like we have never known.

Unfortunately, my projections have come true: we are presently in the throes a brain drain that should be frightening to Americans. Our best students are returning to Asia and even Europe to embark on research careers solely because there are so few academic positions available for them in the United States due the lack of federal research support. Equally alarming is the loss of key US-based nanotechnology faculty to the South Korea, China, Singapore and Australia. I formerly testified that university researchers are industrious folks, and the most astute among them would rather move abroad than to see their prized research programs close. This is now happening. The trolling by foreign universities upon top U.S. faculty has become rampant due to the decline of federal funding levels on a per faculty-member basis. This brain drain is not something from which we can easily recover—the impact of what has already been lost will last decades.

As university research programs shrink substantially or close down, there will be a diminishing supply of US-trained and US-national scientists and engineers. Certainly, we can hire from abroad, but that's not so easy for some industries, such as in the aerospace sector.

My suggestion is the rapid initiation of a \$200MM per year program administered over four years through the standard federal science funding agencies in \$5MM to \$10MM per year multi-investigator programs wherein there is strong in-kind university and corporate partner matching

in dedicated facilities, equipment and personnel. That way the federal money is leveraged to produce 50% more from university development campaigns and industrial partners. Programs like NSF's Innovation Corp assist in the translations of technology to industry.

Next, keep our start-up companies in the US. My last three companies were started abroad, but if the US corporate tax rate were reduced to 15%, we'd gladly remain in the US.

Finally, streamline the Green-Card process for scientists and engineers that receive their PhDs in the US. We need them!

In summary, in the area of graphene research and capture of its intellectual property, the US is not leading, but I think we could lead with a little help from the federal government. It would be a small investment, in the scheme of things, and a major advance for the country. The loss that is unrecoverable for decades is the loss in top talent that has occurred over the past 5 years due to the declination of research support. Personally, I can survive and even thrive for the next 15 years of my career through my network of corporate connections that I have established over the decades. But that cannot be said for the younger and less established researchers in this country. On their behalf, I respectfully urge our congressional leaders to take a long-term vision to reestablish funding to the per-investigator level that we enjoyed 20 years ago and provide the yearly additions needed to keep pace with inflation costs. If our congressional leaders would do that, we'd present strong completion to Asia and we'd win. Please, help us.

#### References

- 1. 1.Partridge, M. "The miracle material that could change the world," *Money Week*, 27
   January, 2017, Issue 829, pp 24-26.
- Seven Sigma Innovation, "Graphene patent and technology landscape analysis. Making sense of an industry disrupting material," 2016.

Mr. LATTA. Thank you very much, I appreciate your testimony. Mr. Murphy, you are recognized for 5 minutes.

#### STATEMENT OF KEITH MURPHY

Mr. Murphy. Thank you. Good morning, Chairman Latta, Congresswoman Matsui, and members of the subcommittee. Thank you for inviting me today to discuss Organovo and the capabilities of our 3D bioprinted human tissue models. Bioprinted 3D human tissue models are disrupting the drug discovery process, because they give researchers and regulators new testing tools and capabilities to make drug discovery safer, speedier, more likely to find breakthrough drugs in new areas, and less costly, and because they enable future implantable tissue therapies to restore or cure failing organ function and address the long waiting list for organ transplant.

What is 3D bioprinting? An office printer uses ink to print on paper; and industrial 3D printers use liquid, plastic, or metals to print machine parts or prototypes. We at Organovo use human cells to make bioink that is deposited by a bioprinter which layers the bioink onto a surface to form organic, living 3D human tissue. Bioprinted model tissues have been shown to replicate the key elements, architecture, and function of living, native human tissues. Bioprinted tissues for transplant have been demonstrated to have powerful potential to treat serious illness by direct transplant into

patients.

I have submitted slides along with the written testimony that will help you visualize the manufacturing process, where we fit into the current drug discovery process, the current progress in transplantable tissues, and examples of the peer-reviewed data we have

used to validate the capabilities of our bioprinted tissues.

Founded in 2007, Organovo is based in San Diego, California, and has grown from the back room of my house—we couldn't afford a garage—to be 120 employees and 45,000 square feet in 10 years. We perform research, build 3D bioprinters, print tissue models, and run our testing services out of our headquarters building, which Congresswoman Walters has visited.

Our customers and partners include almost half of the world's top pharmaceutical companies and leading academic research centers. There is diversity of organ tissues to replicate—liver, kidney, and others—and potential commercial applications beyond drug discovery, such as cosmetics and chemical testing. There are wideranging applications for the Department of Defense, including everything from delivering testing tissues for developing protections against biological attack to creation of tissues to replace function less by wavenings.

lost by wounded warriors.

From 1990 to 2010, 73 percent of phase 3 clinical trials failed due to toxicity or lack of efficacy. In 2012 alone, 10 late-stage clinical trial failures cost innovators \$7 to \$10 billion in losses.

Organovo's 3D human tissue models are currently being used by drug manufacturers to give researchers the ability to look to see if the drug is working, how it is being metabolized over time, and whether it is producing toxic side effects. These models are also being used to help improve the safety and efficacy of potential drugs currently progressing through human trial phases.

3D human tissue models also can be used to help improve the post market safety understanding of approved products. For example, a recent study using 3D bioprinted liver tissues modeled druginduced liver injury to investigate the effects of Trovafloxin, a drug withdrawn from the market due to acute liver failure in patients. The study found that 3D bioprinted liver tissues identified significant Trovafloxin liver toxicity after just 7 days of exposure. In contrast, Trovafloxin did not show strong toxicity signals in common traditional 2D in vitro systems, or in animal models.

A December paper coauthored by the head of FDA's Center for Toxicological Research concluded that both researchers and regulators should prioritize and quickly adopt the use of 3D bioprinted

human tissue models.

We are pleased that both the 21st Century Cures legislation and the draft Prescription Drug User Fee Act (PDUFA) VI agreement take steps to encourage the use and adoption of new drug discovery tools. However, it should be fine-tuned to accelerate the adoption of currently available technologies with existing validating proof versus longer-term technologies not yet available.

We are grateful that committee members introduced legislation, the Patient Safety and Toxicology Modernization Act, requiring FDA to issue guidance by the end of 2018. We hope that the committee includes this legislation in PDUFA VI, to ensure FDA prioritizes adoption of commercially available and proven discovery tools that can speed and lower the cost of drug discovery.

Organovo's 3D bioprinting technology also is being used to develop first-in-class implantable tissues that cure or meaningfully restore a patient's organ function. There remains a tremendous gap between patients waiting for organ transplants and those who receive them. In 2015, roughly 120,000 Americans were waiting for an organ transplant and only 30,000 patients received them.

Organovo's data shows survival and sustained functionality of our 3D bioprinted human liver tissue when implanted into animal models. Our implantable tissue showed encouraging evidence of the potential to restore organ function and to treat inborn errors of metabolism.

The FDA will soon have cell-based bioprinted tissue therapy applications under review. We are grateful that the 21st Century Cures legislation not only created a new regenerative medicine pathway at FDA without lowering safety standards, but also provided greater clarity on how FDA will review so-called combination products. Global regulatory agencies in Europe and Japan already have implemented regenerative medicine pathways. FDA's clear, timely, and collaborative implementation of relevant 21st Century Cures provisions will help ensure that regenerative medicine innovation, research, and clinical trials remain in the U.S.

Thank you again for inviting me to participate in today's hearing. I am happy to answer questions related to my submitted testimony or slides.

[The prepared statement of Mr. Murphy follows:]

#### Keith Murphy

President and Chief Executive Officer

Organovo, Inc.

United States House Energy and Commerce Committee

Subcommittee on Digital Commerce and Consumer Protection

"Disrupter Series: Advanced Materials and Production"

March 15, 2017

#### I. Introduction

Good morning Chairman Latta, Ranking member Schakowsky, and members of the Subcommittee. Thank you for inviting me today to discuss Organovo and the capabilities of our 3D bioprinted human tissue models. Bioprinted 3D human tissue models are disrupting the drug discovery process because they give researchers and regulators new tools and capabilities to make drug discovery safer, speedier, more likely to find breakthrough drugs in new areas, and less costly. Bioprinting also enables future implantable therapies to restore or cure failing organ function and address the long waiting lists for organ transplant.

#### II. What is 3D Bioprinting?

An office printer uses ink to print on paper, and industrial 3D printers use liquid plastic or metals to print machine parts or prototypes. We use human cells to make "bio ink" that is deposited by a "bio printer" which layers the bio ink onto a surface to form organic, living 3D human tissue. Bioprinted research model tissues have been shown to replicate the key elements, architecture, and function of living native human tissues. Bioprinted tissues for transplant have been demonstrated to have powerful potential to treat serious illness by direct transplant into patients. I have submitted slides along with the written testimony that will help you visualize the manufacturing process, where we fit into the current drug discovery process, the current progress in transplantable tissues, and examples of the peer reviewed data we have used to validate the capabilities of our bioprinted tissues.

#### III. What are 3D Human Tissue Model Capabilities to Speed Safer Drugs to Patients?

Our 3D human tissue models are currently disrupting drug innovation in three essential ways:

- providing commercially available 3D human liver and kidney models that effectively bridge the gap between preclinical (animal) testing and clinical (human) trials to improve the predictability, safety, and speed of the discovery process while also lowering the cost of bringing new therapies to patients;
- modeling known diseases, often for disease without good models today where patients lack available therapies, to help researchers best target potential medicines; and
- platform technology needed to develop first in class implantable regenerative medicine therapies that will one day meaningfully restore or cure failing organ function.

#### IV. Company Background

Founded in 2007, we are in San Diego, CA and have grown from 7 to nearly 120 employees in 10 years. We perform research, build 3D bioprinters, print tissue models, and run our testing services out of our 45,000 sq. ft. headquarters building. Our customers and partners include almost half of the world's top pharmaceutical companies. To date we have overcome the challenges of starting, funding, commercializing and growing a small business to develop 3D bioprinted platform technology with multiple potential applications. There is a diversity of organ tissues to replicate (liver, kidney, cancer tumor models, lung, skin, etc...) and potential commercial applications beyond drug discovery — such as cosmetics and chemical testing. There are wide ranging applications for the Department of Defense including everything

from delivering testing tissues for developing protections against biological attack to creation of tissues to replace function lost by wounded warriors.

Recognizing the broad potential, we have partnered with a number of top academic centers across the country who now use our bioprinters on site – including one at the National Institutes of Health (NIH). Our primary business is not selling printers, but we work closely with qualified partners so that they can perform specialized research projects – such as bioprinted breast cancer tumor models built at Oregon Health Sciences University or cardiovascular tissues at Yale University School of Medicine.

#### V. Disrupting the Drug Discovery Process for Researchers and Regulators

From 1990 to 2010, 73% of phase 3 clinical trials failed due to toxicity or lack of efficacy. In 2012 alone, 10 late stage clinical trial failures cost innovators \$7-10 Billion in losses. In addition to drug companies seeking to make the discovery process more efficient and predictive, the Food and Drug Administration (FDA) also has recognized the need for improved drug discovery tools. A 2011 report by FDA, entitled "Advancing Regulatory Science at FDA", prioritized toxicology testing and the development of models of human adverse response as one of the areas of regulatory science where new or enhanced engagement by the agency is essential to the continued success of the public health and regulatory mission.

While the regulatory landscape has remained static, Organovo's 3D human tissue models are currently being used by innovators as a high content screening tool to improve so called "lead candidate selection" — essentially help prioritize which therapies should progress from the lab to human clinical trials. A high content screening effectively allows researchers the benefit of an organ biopsy in a dish without having to take one from an actual patient. Our tissue models give researchers the ability to look to see if the drug is working, how it is being metabolized over time, and whether it is producing toxic side effects. These models also are being used to help improve the safety and efficacy of potential drugs currently progressing through human trial phases.

Over the last few years, we have developed a breadth of peer reviewed data on our own and in collaboration with our research partners. We have been able to show that 3D human tissue models:

- Closely mimic human tissue composition and physiology including biochemical and histologic outcomes;
- Retain key aspects of native human liver for at least six weeks;
- Capture complex multi-cellular events that are not typically captured by traditional 2D in vitro systems; and
- Can detect the liver toxicity of about 70% of the compounds that have historically not been
  predicted to be liver toxic and thereafter had a surprising failure during development or
  withdrawal post-marketing.

Just this week, we released even more data about our liver and kidney tissue models capabilities at the Society of Toxicology Conference in Baltimore<sup>ii</sup>.

We also believe 3D human tissue models can be used to help improve the post market safety understanding of approved products. The attached slides give validating examples where our 3D human tissue models are proven to show toxicity signals for drugs approved and later identified by the FDA as well as no toxicity signals in approved drugs that are proven to show no toxicity signs in humans.

For example, a July 2016 peer reviewed study using 3D bioprinted liver tissues modeled drug-induced liver injury (DILI) to investigate the effects of Trovafloxin – a drug withdrawn from the market due to acute liver failure in patients.<sup>IV</sup>

- This study by researchers from Organovo and Roche found that 3D bioprinted liver tissues identified significant Trovafloxin liver toxicity after just seven days of exposure.
- In contrast, Trovafloxin does not show strong toxicity signals in common traditional 2D in vitro systems. The study provided new evidence that 3D bioprinted tissues can better model the effects of chronic drug dosing or conditions that develop over extended periods of time.

In addition to bioprinted liver tissues, we recently introduced a kidney model for our customers that can model renal toxicity. Detecting kidney toxicity previously has been very difficult to model in vitro. Most researchers still rely on non-human animal models. Our tissue level construction and architecture allows for study of complex drug-induced phenotypes involving multiple cell types. We can provide a number of toxicity readouts including clinically relevant renal injury biomarkers.

Just last year, National Institutes of Health (NIH) Director Francis Collins predicted before the Senate Appropriations Committee that 3D bioengineered tissue will soon speed drug discovery, improve its safety, lower its cost, and largely replace the need for animal testing. Furthermore, a December paper co-authored by the head of FDA's Center for Toxicological Research (NCTR), an Associate Vice President of Toxicology at Merck, and an esteemed researcher in liver biology from Life Net Health not only showcased our technology's capabilities but also its relevance to modernizing the drug discovery process. It identified 3D human tissue models represent the future for "candidate selection" where companies must prioritize drug candidates and resources needed to progress from pre-clinical to phase 1 human trials.

The authors validate the innovative role Organovo's 3D human tissue model capabilities can add to the drug discovery process: "Bioprinting technology that recently has been developed represents a significant innovation in the study of drug-induced liver injury (DILI), as it addresses many of the shortcomings associated with traditional in vitro culture models and animal models." They also state that 3D bioprinted tissues "exhibit a broad range of highly differentiated in vivo like features and functions."

The authors reference results from Organovo's drug-induced liver injury studies that have shown "very good reproducibility and concordance with observed outcomes in vivo at the functional and histological levels" and that treatment of the bioprinted human liver model with known fibrotic agents "mimicked closely that of patient liver samples with drug-induced fibrosis."

The authors conclude that both researchers and regulators should be adopting the use of the 3D bioprinted human tissue models: "The insertion of such high performing, accurately predictive, well-qualified assays for DILI prediction at the right stage and in the appropriate context can favorably impact drug development to enhance success, shorten timelines, reduce the needless use of animals, provide more value from each animal study (and human trial) that is conducted, and help to reduce overall costs by spotting and weeding out compounds with liabilities earlier. It is imperative that we step up quickly to the challenge of prioritizing the most promising tools, evaluating performance critically and collaboratively,

and qualifying and integrating these tools wisely to improve success and reduce needless waste of animals."

We are pleased that both the 21st Century Cures legislation and the draft Prescription Drug User Fee Act (PDUFA) VI agreement take steps to encourage the use and adoption of new drug discovery tools. However, they can be fine-tuned to accelerate the adoption of currently available technologies, with existing validating proof, that can be impactful by driving wider adoption as quickly as possible versus longer term technologies that will not be ready for use until PDUFA VII or later. In addition to being "ready to go', FDA should also prioritize adoption of models that are proven to detect toxicity not identified in non-human animal models or detect or predict toxicity of known clinical failures.

We are grateful that Committee members led by Congressman Chris Collins (R-NY) introduced legislation last year -- the Patient Safety and Toxicology Modernization Act, requiring FDA to issue guidance by the end of 2018 regarding the development and use of novel tools for toxicology and efficacy testing including, but not limited to, three-dimensional human tissue models. The guidance should address the use of such models for preclinical, clinical, and post-market safety and efficacy testing, labeling, or other uses by product sponsors and the Food and Drug Administration. We hope that the Energy and Commerce Committee includes this legislation in PDUFA VI to ensure FDA prioritizes adoption of commercially available and proven discovery tools that can speed and lower the cost of drug discovery.

#### VI. Regenerative Medicine Therapies to Restore Organ Function

Organovo's 3D bioprinting technology also can be used to develop first in class implantable tissue therapies that cure or meaningfully restore a patient's organ function. Advancement of such therapies will help close the gap between patients who are waiting for organ transplants and those who actually receive them. In 2015 there roughly were 120,000 Americans waiting for an organ transplant and just 30,000 transplants performed<sup>vi</sup>. These statistics do not include those not allowed on the list in the first place.

Organovo recently presented data showing survival and sustained functionality of our 3D bioprinted human liver tissue when implanted into animal models<sup>vii</sup>. The preclinical data showed:

- rapid vascularization and tissue engraftment, and evidence of function and durability of our 3D bioprinted human liver tissue over several weeks;
- evidence of stable production of key human liver proteins in the animal bloodstream, and tissue staining for key human metabolic enzymes; and
- the capability of this tissue to potentially treat inborn errors of metabolism.

The FDA will soon have cell-based bioprinted tissue therapy applications under review. We are grateful that the 21st Century Cures legislation not only created a new regenerative medicine pathway at FDA without lowering safety standards, but also provided greater clarity on how FDA will review so called combination products. One way to enable bioprinted tissues to impact the greatest number of patients in the fastest prudent time frame is to continue to pursue regulatory clarity for regenerative medicine products, in particular tissue-based biological products currently regulated by CBER. Global regulatory agencies in Europe and Japan already have implemented regenerative medicine regulatory pathways.

Clear, timely, and collaborative implementation of relevant 21<sup>st</sup> Century Cures provisions will help ensure that regenerative medicine innovation, research, and clinical trials remain in the U.S.

We look forward to working with the Committee and FDA to ensure that these life-saving provisions are implemented thoughtfully to make sure companies like Organovo understand what data is needed to successfully speed these first in class therapies safely to patients.

Thank you again for inviting me to participate in today's hearing. I am happy to answer questions related to my submitted testimony or slides.

#### **About Organovo**

At Organovo, we design and create functional human tissues using our proprietary three-dimensional bioprinting technology. Our goal is to build living human tissues that are proven to function like native tissues. With reproducible 3D tissues that accurately represent human biology, we are enabling ground-breaking therapies by:

- Partnering with biopharmaceutical companies and academic medical centers to design, build, and validate more predictive in vitro tissues for disease modeling and toxicology.
- Giving researchers and regulators something they have never had before the opportunity to
  test drugs on functional human tissues before ever administering the drug to a living person;
  bridging the gulf between preclinical (animal) testing and clinical (human) trials.
- Creating functional, three-dimensional tissues regenerative medicine therapies that can be implanted or delivered into the human body to repair organ function or replace damaged or diseased tissues.

#### **About Keith Murphy**

Keith Murphy, Chairman and Chief Executive Officer

Keith Murphy co-founded Organovo in 2007 and has led all company operations since that time. He co-invented the company's NovoGen MMX bioprinter platform and grew the company through early investments and corporate partnerships. Since going public in 2012, the company has focused on the development of three-dimensional liver, kidney, and cancer tissues. The most advanced program, liver tissue, has grown to encompass a range of applications from commercial use for pharmaceutical toxicology prediction to the preclinical development of human 3D liver patches for transplant patients. Prior to co-founding Organovo, Mr. Murphy spent 15 years in biotech, including ten years at Amgen in roles of increasing responsibility, with four years as the Global Operations Leader of denosumab, now marketed as Prolia & Xgeva (\$3B+ annual sales). He holds a B.S. in chemical engineering from the Massachusetts Institute of Technology and is an alumnus of the UCLA Anderson School of Management. He currently serves on the Boards of the Torrance Memorial Medical Center Foundation and the California Life Sciences Association.

<sup>&</sup>lt;sup>1</sup> FDA.gov; Pharmaceutical Research Manufacturers of America, Profile 2011; EvaluatePharma; Parexel Sourcebook 2012; CDER Report to Nation; Tufts Center for Drug Discovery

<sup>&</sup>lt;sup>ii</sup>Advancing Regulatory Science at FDA

https://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RegulatoryScience/UCM268225.pdf

<sup>&</sup>quot;Organovo and Its Customers Present Data Supporting 3D Bioprinted Liver and Kidney Tissues for Drug Toxicity Testing http://ir.organovo.com/phoenix.zhtml?c=254194&p=irol-newsArticle&ID=2253403

<sup>&</sup>lt;sup>IV</sup> Bioprinted 3D Primary Liver Tissues Allow Assessment of Organ-Level Response to Clinical Drug Induced Toxicity

In Vitro http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0158674

\*The Promise of New Technologies to Reduce, Refine, or Replace Animal Use while Reducing Risks of Drug Induced Liver Injury in Pharmaceutical Development https://academic.oup.com/ilarjournal/article-abstract/57/2/186/2806701/The-Promise-of-New-Technologies-to-Reduce-Refine

vi Organ Donation Statistics https://www.organdonor.gov/statistics-stories/statistics.html

vii Organovo Presents First Preclinical Data on 3D Bioprinted Human Liver Tissues at TERMIS-Americas Meeting http://ir.organovo.com/phoenix.zhtml?c=254194&p=irol-newsArticle&ID=2229241

Mr. LATTA. Well, thank you very much. We appreciate your testimony.

And at this time, we will recognize Dr. Rabiei for 5 minutes for your statement. Thank you very much.

#### STATEMENT OF AFSANEH RABIEI

Ms. RABIEI. Good afternoon. Thank you very much for the invitation. It is an honor to be here and to introduce our material. I decided to use my slides because I believe that seeing is believing. So it is a new material. I am very excited to see that there is an attention to advanced materials.

My name is Afsaneh Rabiei, and I am a professor at North Carolina State University, and there is a link to my Web site for more information about what we are doing.

We are learning from nature, and the art of engineering is to watch what happens in nature and learn from it. So if you look at the slides, we have our brain encapsulated in skull, which is a porous material, bird's wing, leaves, bone, trees. Everything is benefiting from a porous structure filled with air. And speaking of air, earth is surrounded by that to protect us against meteoroids and radiation and heat and so forth.

So how do we learn from it by using Styrofoam or bubble wrap to carry fragile materials, or just carrying a hot beverage using Styrofoam. So how did I learn from it? We used the generous support, like Congresswoman Matsui mentioned, to have almost \$2 million funding to start building a new material, something that is more or less like a metallic bubble wrap.

When you put them side by side, you can see the similarities. It is much lighter than steel. This scale shows two pieces of steel. One is regular steel and the other one is our composite metal foam steel. And it is a third of weight. It is the same size, but the density is a third. And the material has shown a huge energy absorption capability and performing like sponge. It can be used for high-speed impact protection. It can be used for ballistic or blast and frag protection. It can be used for radiation shielding or heat or sound and vibration shielding.

So the possibilities are endless. So the \$2 million is just a drop in an ocean. If we want to get this material in the hands of our soldiers to benefit from its protection, we really need more support.

Here, you probably have seen the picture in a lot of media news coverage, Fox News, Huffington Post, and so forth. In this video, we see the composite metal foam being squeezed down. Of course, the force is huge. What you see is like a kitchen sponge; it is squeezing down, and that is what provides us the energy absorption. This video also shows a composite structure partly made by our composite metal foam. The bullet is hitting the material. It is totally disintegrating.

The panel that you see here in this picture is just 1 foot by 1 foot. It shows a multishock capability that other armors are not providing. This picture is beautiful. If you see, we have the hard core of a bullet entrapped inside those squeezed bubbles. So it basically works as a bubble wrap, but a heavy-duty one.

So the back of the armor also is showing just a small indentation. And if you remember, the National Institute of Justice have up to 44-millimeter indentations, which basically, you stop the bullet but you hurt the soldier by those huge indentations in the back of the armor. This one does have a very small indentation, as you can see, less than an eighth of an inch.

Here, we put this in front of a large HEI 23-millimeter blast and frag, the panel, less-than-an-inch panel. I put a piece of aluminum with the same weight and our material. The red one that you can see totally stressed is aluminum; and the one that is green and happy is our material. So you can put it under the vehicle, in a vehicle, armor. You can put it anywhere to protect our soldiers, and I bet they are going to be much happier.

The cross-section also is shown, and the aluminum has been damaged a lot and composite metal bomb stopped all the fragments, stopped the blast wave energy. These particles have been flying up to 5,000 foot per second and they hit the panel, and the panel stopped them.

The rest of it is confidential with Army.

We also learned from our atmosphere, and we put it in front of 800 degrees Celsius flame. And, as you can see, our material takes 8 minutes to reach the saturation of 800 degrees Celsius with just less than an inch thickness. Steel takes 4 minutes, and aluminum takes 20 seconds. So that shows how the material can insulate against heat and protect against high temperatures.

So you can imagine all of the cases, a lot of cargos that carry explosives, things that can be helpful in all directions to protect against heat. And also, we also learned from atmosphere and put it against x-ray. We are not reaching lead yet, but we have shown almost 275 percent improvement in blocking x-ray compared to aluminum

So in our recent studies funded by Nuclear Energy University Program, we have collected those data and we learned that if we add a little bit of other elements into our material, we can further improve it, but we need more support. This has been done in the last decade or so, and I have done all of these single-handed. We need much more funding. If this technology needs to go out and protect our soldiers, our people, we definitely need more support.

I did not notice the time. I am so sorry I took longer.

[The prepared statement of Ms. Rabiei follows:]

### An Introduction to the Novel Composite Metal Foam Materials

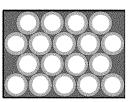
By: Professor Afsaneh Rabiei,

# Department of Mechanical and Aerospace Engineering, North Carolina State University, Raleigh, NC 27695-7910, USA

### arabiei@ncsu.edu

### http://people.engr.ncsu.edu/arabiei/

Introduction: Composite metal foam (CMF) is a novel light weight material created at North Carolina State University. The material is made of metallic hollow spheres closely packed together and the empty spaces in between them filled with a metallic matrix through either casting (of a molten metal) or sintering (of a powdered metal). The hollow spheres are filled with air and provide light-weight





and porosities, while the surrounding matrix works to strengthen the bonding between spheres and blunt any potential cracks in the material under load. Under large amount of compression loading, the spheres collapse and expend the impact energy protecting whatever is behind it. CMF's strength is further improved under higher speed of impact due to the resistance of air inside its spheres (similar to a bubble wrap performance under pressure, but in a much larger scale). Such extra-ordinary energy absorption capabilities of CMFs inspired their application in ballistic and blast armor systems along with many others.

- The product will look like a heavy-duty bubble wrap to protect against larger impacts of train
  or car crash, blast wave and fragmentation, ballistic and more.
- The material contains about 30-40% metal and 70-60% air trapped inside its porosities. As such a100% stainless steel composite metal foam is as light as aluminum (70% lighter than

stainless steel) and a combination of aluminum with steel composite metal foam can be nearly as light as water!

- Composite metal foams have shown nearly two orders of magnitude higher impact energy absorption capability compared to their parent bulk material (such as aluminum or steel).
- High air content inside Composite metal foam offers extremely good thermal insulation
  performance; nearly two orders of magnitude lower thermal conductivity in steel composite
  foams compared to bulk aluminum is observed.
- A 100% Steel composite foam shows almost 275% more effectiveness in shielding X-rays compared to Aluminum.
- Four patents are issued and more are pending on processing of the material through two techniques and
- One start-up company has just shaped to commercialize this material.

Figure shows Composite Steel foam before (left) and after (right) 80% deformation under compression. The sample on the right was the same size as the one on the left before being squeezed to the current size under compression. These samples are 100% made of stainless steel while the air trapped inside its porosities made them 70% lighter than stainless steel.



<u>Funding:</u> Total of ~\$2 M is being used on various projects for creation, evaluation and optimization of the composite metal foams so far. The sources of funding were including:

- NSF (~\$500K) for the first step of creation of the material,
- ARO (~\$70K) for evaluation of material's performance under high speed impact,
- NASA (~\$20K), NC Space Grant (\$20K) & DOE (~\$400K) to evaluate the shielding capabilities of the material against various types of radiation and heat.

- NCSU-Chancellor's Innovation Fund (\$75K) to evaluate the performance of the material in armors
- National Academy of Science along with Transportation Research Board (\$100K) for the evaluation of the material's performance for train's safety.
- Joint Aircraft Survivability Program (JASP) provided \$420K for 2014-2017 for application
  of the material in armors (against blast pressure, fragments and ballistics)
- DOT (\$510K) on application of the material for tank cars transporting hazmat (2016-19)
- NASA (\$31K) for the application of the material on leading edge of airplanes (2017-17)
- Invention has been highlighted as the next generation light-weight material with multiple applications by many news media such as: Fox News, Fox 8,

  Huffington Post, The American Ceramic Society, National Academy of Engineers,
  Science Friday, Popular Mechanics,
  Homeland Defense & Security,
  Information Analysis Center, Physics
  World, US International Information
  Program, Yahoo News KQED, NSF NSF
  Science Nation, Youtube Video, NSF NSF





## Some of the potential applications of composite metal foams include:

- Light-weight armors with high performance against larger caliber bullets with armor
   piercing, blast wave and fragments flying with very high speeds (such as 5000ft/s)
- Structural parts for tanks, Humvees and land system vehicles to improve protection against IEDs, improved crashworthiness, and enabling the vehicles to be maneuverable and fuel efficient.
- Helicopter parts to absorb the impact energy upon hard landing while providing a light-weight solution
- o Crash energy absorbers in trains, cars and buses
- Mine boots and personal armors and helmets
- Medical devices including implants with good stiffness similar to bone that prevents stress shielding and premature failure of implants.
- o Heat protection devices (fire doors, safes, containers,...)
- o Radiation shielding parts with light weight and no toxicity

nside the crushed spheres	7.62 M2 Partial Penetration (in flight)	

Same size steel



# Steel-Steel CMF



This figure shows two pieces of steel and composite steel foam with same sizes. The steel CMF is almost 1/3 of the weight of steel.

For more information about composite metal foams and their properties and applications, please refer to our website at <a href="http://people.engr.ncsu.edu/arabiei/">http://people.engr.ncsu.edu/arabiei/</a>

Mr. LATTA. Well, thank you very much for your testimony. I really appreciate that.

And at this time, we will recognize Dr. GangaRao for 5 minutes. Thanks again for being here.

### STATEMENT OF DR. HOTA GANGARAO

Mr. GANGARAO. Thank you very much, Mr. Chairman. My theme today is going to be on the renovation of American infrastructure with advanced composite materials.

Herein, I do not want to propose rip and replace of existing conventional materials. We want to reinforce them, make them safe. According to last week's American Society of Civil Engineers' report, our infrastructure received a grade of D-plus. This low grade is attributed to \$4.5 trillion over 10-year funding gap between revenue and infrastructure needs. On top of it, motorists are spending \$500 a year per vehicle to maintain, due to the poor quality of our bridges and highways.

Where could we get the funding from? Public-private partnership. We have been doing that, to a small extent, and as you have seen, I-267 outside D.C. More debt to our \$20 trillion debt package. Not sure that the Congress wants this up. Increasing Federal and State gas taxes. That I am afraid doesn't have the appetite of the Congress

I have a fourth idea: Do not rip and replace, but renovate with advanced composite materials. Here are some of the composite materials that we at the Constructed Facilities Center of West Virginia University have been developing since 1987. Thanks to Congressman McKinley, we built a bridge in his backyard back in 1996. It is standing, functioning extremely well, with a reinforcing bar in lieu of the steel bar. This is four times lighter, two times stronger, noncorrosive, nonconductive. I have several materials to that effect.

These developments have taken place in cooperation with government agencies, a wide range of industries, and academia. To illustrate West Virginia University activities with government and industry help, we have built over 100 new bridges, including laminated composite timber, polymer, and glass or carbon composites. And also, we did some of the hybrid development, implying the wrapping of concrete and timber with composite. And these approaches do not call for any rip of the existing commodity product, but reinforce these products with glass or carbon as a shell with conventional materials as a substrate or a core.

Today, I want to focus on discussions on saving huge sums of money for taxpayers without compromising safety or user inconvenience. Allow me to use three great examples to illustrate my savings plan. Say, for example, we will focus on transportation infrastructure. One is the bridge deck systems. These are the first lines of defense when it comes to structural material deterioration of bridge superstructures. This is a \$120 to \$150 billion problem. We can remove this falling concrete and do a few other things, and put a glass or a carbon fabric carpet on top of the existing concrete deck and fuse it with proper resin. Where is the savings? This can be done with about \$50 to \$60 a square foot of a deck while, in fact,

a rip and a replace will cost you about \$150 to \$180 a square foot.

You can imagine the savings.

The second example, we discard 20 million railroad ties that are creosote-treated, and this has a humongous environmental problem. What we propose is put a Band-Aid, known as a glass composite wrap, or a carbon composite wrap, to enhance the service life to about 50 to 60 years, if not 80 years. Imagine the amount of money one can save from—we have done the field testing and also the Pueblo, Colorado, testing, and we have shown that the life expectancy can be tremendously improved.

The third item I would like to talk about is the shale gas movement. West Virginia is the epicenter of gas deposits. With these new composite materials, with nanocoatings made of graphene or whatever that are noncorrosive and nonconductive, we can design pipelines with internal pressures of 3,000 to 5,000 psi, and be able

to push more gas at a most economical price.

I have several other examples. I need to skip a few of them for the sake of time factor. Then the question is, one wonders if these all so good, why the free market is not accepting them? There are several impediments. I will not go into them. In conclusion, those

impediments are clearly stated in my write-up.

However, in conclusion, this is what I would like to say: We are most grateful that the U.S. Government support has been integral in the initial development and implementation of composites in civil infrastructure. With continued support, manufacturers will continue to expand, create high-paying jobs, and improve U.S. infrastructure so that advanced composite materials will be an integral part of our infrastructure landscape.

Thank you very much for the opportunity.

[The prepared statement of Mr. GangaRao follows:]

# - Energy and Commerce Committee Hearing Advanced Material Development and Manufacturing, with Focus on Infrastructure Application

Hota GangaRao, PhD, P.E., F. ASCE, F. SEI

Maurice A. and Jo Ann Wadsworth Distinguished Professor of CEE, CEMR
Director, Constructed Facilities Center
Director, Center for Integration of Composites into Infrastructure
Statler College of Engineering and Mineral Resources
West Virginia University
Morgantown, WV 26506

March 15, 2017, 10:15AM

#### **Current Position Statement**

Efficient infrastructure systems such as highways, bridges, buildings, pipelines, flood control systems, and utilities are all necessary for economy growth and a high standard of living. However, our infrastructure is in a dire state, as the American Society of Civil Engineers (ASCE) report card gives the US infrastructure a grade of D+. ASCE attributes the bulk of this low grade to the funding gap of \$4.59 trillion between revenue and infrastructure needs, which in turn costs each household \$3,400 per year (ASCE, 2016). Advanced Fiber Reinforced Polymer (FRP) composite materials offer a more efficient use of taxpayer dollars compared to conventional materials. FRP composites result in a paradigm shift in material usage because of their favorable material properties and enhanced service life, including non-corrosiveness and high strength to weight ratio, thus leading to reduced life cycle costs. The adaptability of FRP composites has led to a wide variety of uses, with many advances in the automotive and aerospace industries. For instance, the use of FRP composites on the Boeing 787 Dreamliner allowed it to be 20% more fuel efficient than its predecessor. FRP composites have been used in infrastructure for over 30 years, including:

- Corrosion resistant reinforcing bars (rebar) for highways with a 90 year service life
- · Bridge decks and superstructures
- · Hazardous material containers and pipelines
- Structures with longer spans (> 10,000 feet span) resulting in reduced self weight
- · Utility poles and towers
- Strengthening and wrapping of in-service structures including navigational structures
- Many others, including composite deck houses for the next generation battle ships.

The United States of America is the largest producer and user of FRP composites and the world leader in composite technology development and implementation. Such leadership is attributed to the major thrust provided by the federal and state government agencies. The shipment of advanced FRP composites in the US is about 5 billion lbs annually with about 32% of share in transportation and 21% in construction.

Over the past 30 years, various federal and state agencies have worked in cooperation with American composites industries to promote and advance the FRP composites for civil infrastructural applications. The automotive and aerospace fields benefit from the ability to build and evaluate many prototypes, thus making the risk factors of the final product minimal. Civil infrastructure instead relies on codes and standard practices built on the lessons learned from many different contractors over years of implementation. As such, the incorporation of new materials is outside the scope of the current codes, which increases the risk and complexity of the project. The US government has played a unique role in accelerating the adoption of advanced composite materials by being a willing participant in the use of these materials for government projects. Indeed, I have been fortunate as the director of the Constructed Facilities Center at West Virginia University to receive funding from the National Science Foundation, US Army Corps of Engineers, US

DOT, and others to implement advanced FRP composite materials into infrastructure. However, there is still work to move these efforts firmly into the private sector, including collecting data on in-service field responses, incorporating this information into design specifications and training engineers to properly use these new materials.

### Research and Implementation

The US government established numerous research programs in FRP composites for civil infrastructure applications to lay the groundwork for the robust data set necessary to allow for widespread field implementation. Work began with laboratory studies of the materials, including accelerated test programs to predict long-term performance of infrastructure systems. In parallel, a number of field demonstration projects have been sponsored to better understand composites under real world field conditions. As with any new endeavor, there have been a handful of less than successful projects, but the vast majority of these one-and-done field demonstration projects have been highly successful and are still in-service, several well beyond their original expected design life. From a scientific standpoint, this government funded work has provided priceless data on the field performance of FRP composites. Additionally, there have been many innovations with material development, efficient structural design, and manufacturing techniques. For example, the most successful story to tell is the evolution of FRP bridge decks, leading to six-fold increase in strength and a three-fold decrease in unit cost of FRP deck components over the past 20 years. A major thrust of recent research has been away from non-renewable petroleum-based products and towards green composites made with renewable plant fibers and US agricultural products such as soy. Another research endeavor is the development of FRP composite pipes for natural gas transmission, thus enabling US energy to reach the market via US-produced pipelines that are corrosion resistant and less susceptible to leaks.

#### **Technology Transfer**

In addition to the major push in terms of fundamental research efforts since 1980s, NSF played a critical role in technology transfer strategies. For example, the Center for Integration of Composites into Infrastructure (CICI), a NSF Industry/University Cooperative Research Center (I/UCRC) program, provides an excellent platform for university and industry interaction. The 30 member CICI industrial advisory board directs collaborative research to benefit the entire FRP infrastructure industry.

### **Design Codes**

The research advances through government sponsored programs resulted in developing numerous private and government codes and design guidelines, including FRP rebar, FRP strengthening of concrete members, and FRP design specifications for pultruded shapes. These codes and specifications would not exist today if not for previous government sponsored work. Advent of these codes will help FRP composites to compete on a level playing field with other construction materials like concrete, steel, wood and aluminum, materials with well-established codes. Performance criteria for design, specification and installation will mean a higher degree of confidence for professional engineers and contractors to design and construct with advanced composite materials, in addition to instilling confidence in owners to field implement advanced FRP composite materials.

### Mass Production of Advanced Composite Materials

Manufacturing of composites is economical at mass scale via factory production using such methods as pultrusion, filament winding, resin transfer molding and sheet molding. Each of these methods has unique advantages, thus the manufacturing method is chosen to best fit the final application. For instance, filament winding is ideal for producing round structures such as flues for smokestacks, while pultrusion is best suited for very high strength structural shapes. Factory manufacturing is most cost-efficient with limited changes to the assembly line, thus costs can be greatly reduced when large quantities can be produced with a given setup. The one-and-done nature of past demonstration projects does not allow for these cost efficiencies to be realized. However, a commitment to specify a large quantity of advanced FRP composites would allow manufacturers to produce in bulk with less risk of excess inventory.

### Additive Manufacturing for Rehabilitation of Constructed Facilities

Additive Manufacturing (AM), also known as 3D printing, is a new manufacturing technique in which successive layers of materials are applied via a robotic armature to create a structure. A number of research groups have been able to use these powerful tools to create high quality complex parts with advanced composite materials. AM has the potential to provide unique ability to research, design, develop, and produce a wide range of "engineered" parts in a matter of hours, including custom prosthetics, industrial grade aircraft and automotive parts, full size electric vehicles and a 6-story concrete apartment building. Additive manufacturing is revolutionizing traditional fabrication and construction methods by producing high quality products with excellent durability characteristics.

In the US, many bridges are currently rated as structurally deficient and in need of repair. Based on recent patent pending work, WVU-CFC has demonstrated that structural integrity can be improved by focusing repairs at strategic locations in complex mechanical/structural systems; we intend to produce such parts insitu to enhance structural integrity of large systems by several hundred percent. The WVU-CFC team further intends to use drones to 3D photograph structurally deficient bridges, buildings, and lock gate systems and then take advantage of 3D printing techniques to retrofit these structures with 3D printed parts, thus enhancing their service life in the most economical manner.

#### Societal Impact

Academia in cooperation with government and industry has made major strides in developing advanced composites for infrastructure applications, including structures for highway and waterway, utility poles, wind turbine blades, and pipelines. These implementation efforts have been driven by recent market acceptance of composites, especially in highway construction. In the state of West Virginia alone, more than 25 highway bridges were built or rehabilitated with advanced composite materials and many thanks to support rendered by NSF, USDOT, and WVDOT-DOH. In addition, the WVDOT-DOH is developing plans that may lead to the rehabilitation of 400-500 concrete bridges using advanced composite wraps in the next 5 years because of their cost effectiveness and minimal user inconveniences.

Government sponsored R&D in composites has opened up large markets for composites in infrastructure. In just the highway system, advanced composites can be used for bridge decks, rebar, dowel bars, stringers, abutments, signposts, signboard, guardrail systems, sound barriers, and drainage systems. Each of these products represents a multibillion potential market and provide a longer service life than conventional materials, thus reducing future government expenses. Similarly, pipelines for gas, water and sewer are a billion dollar annual market, while the utility pole potential market is of an order of 4 billion dollars per year.

### Barriers for Broader Use of Advance Composites

To utilize the advantages of advanced composites, engineering communities need to reduce the ART TO PART gestation period. On February 8-9, 2017, NIST sponsored a workshop with a goal of determining the barriers to widespread adoption of polymer composites for sustainable infrastructure applications. There were 60 participants representing industry, government and academia that were informed by key stakeholders including owners, designers, and contractors on challenges they face in the infrastructure market. Breakout groups representing new construction, repair construction, and stand-alone FRP products used in the infrastructure market collaborated on the 5 most critical barriers to success in that respective sector. The most common barriers identified included training and education, codes and standards, composites durability and service life prediction, and testing. The US government can play a key role in breaking down these barriers by supporting efforts to evaluate in-service FRP composites, which would provide the data needed to evaluate durability and develop specifications.

With recent launching of new design codes, new markets will open up and existing markets will further broaden for the advanced composites industry. The support of the US government has been integral in the initial implementation of advanced composites. With continued support, manufacturers will continue to expand, creating jobs for Americans and improving our infrastructure. Advanced composite materials will become an integral part of civil infrastructure providing the American public benefits in terms of cost effectiveness and reduced user inconveniences due to ease of installation, low maintenance, longer service life, and greener products.

# Field Implementation: Initial versus Life Cycle Costs



Figure 1. Market Street Bridge (Wheeling, WV, built in 2000) with FRP decks (WVU)

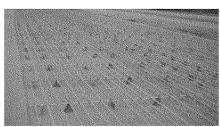


Fig 2. Pavement with FRP Rebar, WV Route 9, Martinsburg, WV (WVU, 2007)



Fig 3. Pavement with FRP Dowels Elkins Corridor H-Project, Elkins, WV (WVU, 2003)





Figure 4. FRP utility poles (BRP, 2010)



Figure 5. 16 inch diameter FRP pipe being tested at WVU-CFC laboratory (2011)

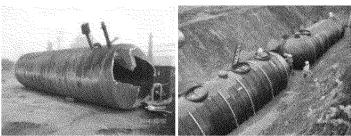


Figure 6. Durable FRP Gas Tanks (Liang, 2014)

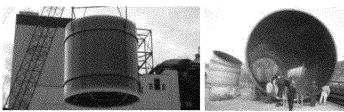


Figure 7. Large diameter FRP chimney flue liner, a) a module liner section and b) connection elbow (Rider, 2009)



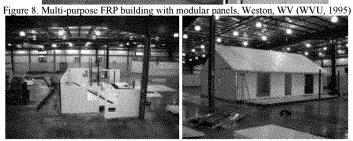


Figure 9. FRP composite house being erected at BRP Inc. manufacturing facility (WVU, 2008)

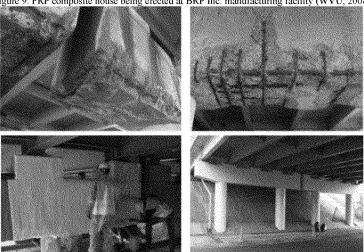


Figure 10. Rehabilitation using FRP wraps of Madison Avenue Bridge, Huntington, WV (WVU, 2014)

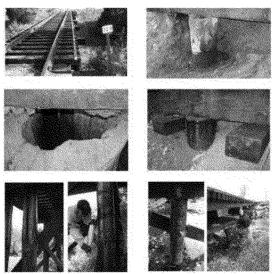


Figure 11. Retrofitting of railroad bridges using FRP wraps, Moorefield, WV (WVU, 2010)



Figure 12. Rehabilitation of corroded steel H-pile bridge using composites, East Lynn Lake Bridge, East Lynn, WV. The repair cost 35% of the cost of a conventional repair. (WVU, 2014)

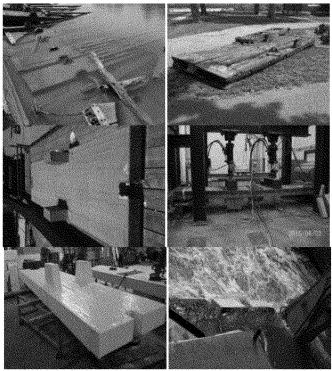


Figure 13. Composite Wicket gates and its field implementation in lieu of deteriorated wood wicket gate. The composite gate is ½ the cost with a much longer expected design life. (WVU, 2015)

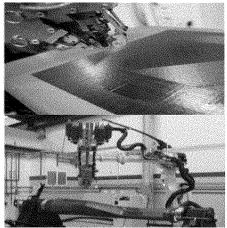


Figure 14: Additive manufacturing of advanced composite materials part, with automatic fiber placement (Cormier, 2016)



Figure 15: 6-story 3D printed apartment building (Sevenson, 2015)

Mr. LATTA. Again, thank you very much for your testimony. And, Mr. Weyant, we will give you 5 minutes now for your opening statement. Thank you for being with us.

### STATEMENT OF SHANE E. WEYANT

Mr. Weyant. Good afternoon, Chairman Latta, Congresswoman Matsui, and the members of the subcommittee. Thank you, and I appreciate the opportunity to testify before you today.

I am testifying on behalf of Creative Pultrusions and my fellow members of the American Composite Manufacturers Association.

Creative Pultrusions is one of over 3,000 manufacturers of composites who are represented by the ACMA. Since World War II, this industry has made products using combinations of glass or carbon fiber reinforcements, and tough engineered polymers. The resulting material is stronger than the constituent materials individually.

Composites provide characteristics specifically tailored for maximum performance in a host of different applications. Composites are stronger than other materials, such as steel, concrete, and wood. They are also lighter, more energy-efficient, and easier to transport, assemble, and install. They offer design flexibility and durability and, most importantly, are resistant to corrosion and structural degradation.

We have been in business for over 44 years and have seen many changes to the industry. Some applications for composites have been disrupters, but are now common practice, like fiberglass boats and windmill blades. The industry has great potential to upend traditional infrastructure and construction markets and address an immediate national challenge.

Nearly every key development in our industry since its inception began in the United States. However, the committee should be aware that other countries have accelerated research and commercialization in an effort to gain market dominance. Policymakers should ensure that disruptive domestic technologies likes ours have a framework and an environment to encourage their continued advancement and adoption, including supporting institutions, such as the advanced manufacturing institutes.

Our energy and communications infrastructure is more critical than ever, yet, it is reliant upon 19th century technology, wood poles. Tens of thousands were wiped out by Superstorm Sandy, and hundreds of thousands of wood poles and crossarms are nearing or past their functional service life. We have a choice to continue with this outmoded technology, or use 21st century material. My company is one of many manufacturers of composite utility poles and crossarms that are easier to install, and more durable against extreme weather, fire, and require less maintenance and last significantly longer.

Composite poles are the best choice in environmentally sensitive areas, because they will not leach toxic chemicals and are resistant to rot and pests. The structural capabilities of composites give these materials the ability to disrupt the 150-plus-year span for building bridges in this country as well, a disruption welcomed by Canadians and other nations.

Composites bring the advantage of extended service life and superior performance through the inherent resistance to rust and degradation. When traditional materials such as steel-reinforced concrete rust, crumble, and spall, composites remain unchanged.

An additional benefit of composites is the speed of production and installation. Traditionally, bridges can take months to build on site. We have installed bridges, with the help of Dr. GangaRao, like the Market Street Bridge in Wheeling, West Virginia, with less than 14 hours of labor to install the bridge deck.

The recent events in Flint and Oroville show our water infrastructure is also in need of modernization. Composite technologies have the capacity to revolutionize the water systems around this country. Composites can provide pipe and structures that are easier to install, stronger, and more durable than the other materials, and are inert, and don't leach chemicals into drinking water.

Composites also have a game-changing potential in marine infrastructure. Our SuperLoc sheet piling system, for example, rehabilitates deteriorated waterfront structures subject to harsh marine environments. A similar product, our fender pile system, was used to rehabilitate the service dock at the Statue of Liberty in wake of Superstorm Sandy, replacing outdated wooden structures.

Standards are a crucial issue. The Federal Government has been instrumental in the development of standards for other industries. Now is the time for Federal agencies to work with us and our academic partners, like my fellow witness, Dr. GangaRao, to develop these standards that would allow us to meet the challenge of our future with innovative solutions.

Thank you for the opportunity to testify today on behalf of the domestic composite industry, and I am happy to answer any questions.

[The prepared statement of Mr. Weyant follows:]

# Statement of Shane E. Weyant

**President and CEO of Creative Pultrusions, Inc.** (on behalf of the American Composites Manufacturers Association)

# Before the Subcommittee on Digital Commerce and Consumer Protection

"Disrupter Series: Advanced Materials and Production" March 15, 2017 Washington, DC





Chairman Latta, Ranking Member Schakowsky and members of the Subcommittee on Digital Commerce and Consumer Protection, thank you for the opportunity to testify before you today. My name is Shane Weyant, and I am the President and Chief Executive Officer of Creative Pultrusions in Alum Bank, PA. On behalf of our company and my fellow members of the American Composites Manufacturers Association (ACMA), I appreciate the opportunity to testify before you today.

Creative Pultrusions is one of over 3000 manufacturers of fiber reinforced polymer (FRP) composites in the United States that are represented under the umbrella of ACMA. The organization provides representation, education, and technical support for companies like mine – almost all small businesses provided good jobs in small towns across America.

We have been in business for over 44 years and have seen numerous changes to the industry over the years. While some applications for composites are widely known – like fiberglass boats for example – the industry has great potential to disrupt traditional infrastructure and construction markets where legacy materials dominate the materials market – holding approximately a 98% market share. The composites industry is a key player in a multitude of high performance segments, such as aerospace, automotive, defense, sports and recreation, and healthcare, but it is our applications within the infrastructure space which have the greatest actionable potential to disrupt current practices and address an immediate and endemic national challenge.

Composites are combinations of fiber reinforcements, most commonly glass or carbon among many other materials, and tough engineered polymers. The resulting material combination is

stronger than the constituent materials individually. Composites are formulated to provide characteristics specifically tailored for maximum performance in a host of different applications.

# **Key Structural Characteristics of Composites**

### Strong

Per pound, composites are stronger than other materials such as steel, concrete and wood. The two primary components of composites – fibers and polymers – contribute to their strength. Fiber reinforcements carry the load, while the polymer network distributes the load throughout the composite part as designed.

### Lightweight

Composites are light in weight compared to most woods and metals. But why is lighter better? Lighter objects, ranging from utility poles to bridge decks, are more energy efficient and easier to transport, assemble and install. Both of these features result in lowering costs.

### Resistant

Composites resist damage from exposure to weather and harsh chemicals that can degrade other materials. This makes composites a superior choice for applications that face constant exposure to salt water, corrosive chemicals, extreme temperature and other severe conditions.

### Design Flexibility

A wide range of material combinations can be used in composites, which allows for design flexibility. The materials can be custom tailored to meet performance requirements or fit unique specifications of each application. Composites can also be easily molded into complicated shapes, reducing the number of individual components resulting in faster assembly and a reduced potential for damage during service life.

### Durable

Structures made with composites are robust with a long life that will require little or no maintenance. Many products made with composites have been in service for more than half a century.

### Environmentally Friendly

Composite structures require significantly lower amounts of energy to be produced than traditional construction materials such as steel, aluminum and concrete. In addition, the resulting structure is chemically inert and will not degrade or leach harmful substances into the environment.

### The Pultrusion Process

There are dozens of ways to manufacture composites. At Creative Pultrusions we utilize the pultrusion process, a unique method that we have spent decades perfecting for maximum performance of our products.

Continuous fiber reinforcements such as glass fiber, carbon fiber or basalt fiber roving, mat, and a surfacing veil are positioned on a rack at the beginning of the process, and a complex series of tensioning devices and guides direct the roving into the die which is impregnated with resin and then pulled (therefore the term *pul*-trusion) through a steel die by a powerful tractor- pull mechanism. The steel die consolidates the saturated reinforcement, sets the shape of the product, and controls the fiber/resin ratio. The die is heated to rapidly cure the resin. The process is automated and operates continuously.

In the following sections, I will elaborate on some specific, but by no means all, examples of the capabilities composites bring to key infrastructure applications. It is important to note that while specific examples from Creative Pultrusions product lines are offered here, many companies offer similar products around the country and around the world.

# Capabilities for Electricity Infrastructure

American lives rely on continual and reliable access to power. While the energy economy has moved into the 21<sup>st</sup> century, the underlying infrastructure supporting the national electric grid has changed very little since the 1800s. With hundreds of thousands of wood poles and cross arms nearing or past their functional service life, now is the time to think critically about strengthening the infrastructure that powers the American economy and our daily lives.

The economic damage caused by grid failures is significant, and extends far beyond the grid itself. Property damage from electric grid failures includes not only damage to the power infrastructure and equipment, but residual losses of food and pharmaceuticals, an inability to move manufactured goods, and nonfunctioning critical services such as those provided by hospitals. An outage-induced lack of mass transit, traffic lights, electronic tolling stations, and retail cash registers are only a few of the costly interruptions to the normal flow of business. Finally, losses also come in the form of recovery costs related to backup power provision, temporary housing, litigation and other expenses.

Through our Powertrusion line, Creative Pultrusions is one of several manufacturers of composite utility poles and cross-arms. Electric grid systems that rely on FRP composite utility

poles and cross arms find superior performance on every front—durability, strength, flexibility, service life and resistance to natural weather threats. Maintenance-free composites can revitalize and harden the electric grid, making it more reliable and resilient in the face of storms, reducing outages, and enabling faster service restoration after storms and other natural events.

FRP composite poles are the best choice in environmentally sensitive areas such as coastal areas, wetlands and bogs, because they will not leach toxic preservatives into the environment.

Composites are also resistant to rot, termite and ant damage as well as destruction from other pests. FRP poles are resistant to one of the primary threats to wood poles--woodpeckers. Because FRP poles are immune to these factors, they are the most environmentally sound, long-term solution in environmentally-sensitive areas.

Wildfires, especially common in the Western U.S. during summer months, can run rampant through dry bush, destroying wood poles and causing interruptions to the power grid. In areas that experienced wildfires, wooden utility poles are burned to the ground but the composite poles are still standing, with their structural integrity still intact.

An additional key attribute is non-conductivity. This non-conductivity is particularly important when comparing FRP poles to other utility pole materials—wood is potentially conductive, especially when wet; steel is conductive; and concrete is conductive because of its steel reinforcement. The low conductivity of FRP makes them safer for linesmen, especially when speed is essential to restore grid operations.

Some FRP composite poles can cost more to purchase than wood poles, however, when

amortized over the life cycle of the pole, FRP composite poles are a better long-term solution and help utility companies realize significant savings. FRP poles not only last two to three times longer than wood poles, they also create savings in during installation, maintenance, repair, transportation, replacement, and disposal. One FRP composite pole with an approximate service life between 60 and 80 years, equates to about two to three wood poles that have an estimated service life between 20 to 40 years.

Composite poles can prevent what is known as a cascading effect. If a wood pole is blown down by wind, the attached wires can pull down adjacent poles, and this effect can cascade for a distance along a line. By replacing as few as one of every five wood poles with a composite pole, the entire line is strengthened and cascading will be prevented.

FRP composite cross arms are another key application. They do not need to be replaced as frequently as wood cross arms, which are more prone to deterioration and mechanical damage. Linemen also have an easier job replacing lighter FRP composite cross arms. Wood cross arms are heavier and may be unwieldy, especially if the lineman is working at the top of a pole. As a result, repairs to wood poles and cross arms may create a workplace hazard risk that is mitigated with lighter and safer composites.

# **Capabilities for Surface Transportation Infrastructure**

As the American Society of Civil Engineers notes in their Infrastructure Report Card (www.infrastructurereportcard.com), the state of roads and bridges around the country is woefully inadequate. Traditional materials used to build, repair and maintain our infrastructure

are failing to provide the long-term performance and reduced maintenance costs needed to support a 21st century population and economy.

The structural capabilities of composites give these materials the ability to disrupt 150+ year standard for building bridges in this country, a disruption welcomed by many other countries including our Canadian neighbors. Creative Pultrusions has installed numerous bridge decks and bridge reinforcement components over the last few decades, as have a multitude of other composite manufacturers. Pultruded or molded bridge decks made of composites have traditionally been anchored by short and medium span structures, however additional materials research and standards development are increasing the capability for their use in longer spans. Composites bring the advantage of extended service life and superior performance through inherent resistance to corrosion and structural degradation. When traditional materials such as steel reinforced concrete crumble and spall, composites remain undamaged. Composite rebar used to reinforce concrete bridge superstructures is another key application in this market. Composite rebar is cost competitive with standard epoxy coated steel rebar, with the added advantage of complete corrosion resistance. When concrete bridges are seen in crumbling disrepair it is generally due to corrosion of the underlying steel reinforcements that cause the bars to expand and the concrete to crack. Composites avoid this problem and add decades of service life to critical infrastructure.

An additional benefit for composites in the bridge market is the speed of production and installation. Traditionally, bridges take several weeks, and even months, to build onsite. With prefabricated composites, the same bridge can be fabricated offsite and installed in less than a

day, often in just a few hours. This reduction of construction time results in reduced disruption of traffic and commerce that can be critical, especially in rural and remote areas.

The Innovative Bridge Research and Construction Program (IBRC), a former US Department of Transportation program authorized from 1998 through 2003, funded the construction of approximately 150 bridges that deployed composites in one way or another among more than 300 bridges deploying a host of other innovative materials. The Fixing America's Surface Transportation Act of 2015 directed the Federal Highway Administration to contract with the Transportation Research Board to study the performance of the IBRC bridges. The results of the study will be critical to demonstrating authoritatively how innovative materials like composites can disrupt traditional construction and build stronger infrastructure.

## Capabilities for Water Treatment Systems and Distribution

The recent events in Flint and other locales illustrate a major problem with respect to our water infrastructure. Even in the United States, the delivery of clean drinking water remains a significant problem for federal, state and local agencies. Water and wastewater treatment facilities and water delivery networks in many municipalities are in need of a complete overhaul. Even in systems that are better than others, maintenance costs continue to climb as conventional materials like steel and wood fail to perform adequately in an environment predominated by highly corrosive chemicals.

Composite technologies have the capacity to revolutionize water systems around the country because of their corrosion resistant properties. While composites have been used successfully in

water and waste water applications for decades, they remain under-deployed as many authorities continue to replace aging infrastructure with outdated, and often inferior, technologies. Pultruded grating, baffles, and panel systems fully withstand any degradation from corrosive chemicals. Because of their properties, composite pipes are also used in desalination plants, particularly in drought prone areas.

In addition, a unique process called Cured In-Place Pipe allows for a new composite pipe to be produced onsite within the walls of the failing pipe structure. This system is a transformative change from traditional methods of water distribution rehabilitation, as it can create several hundred feet of new pipe from a single small opening and eliminates the need to tear up roads and curtail traffic and commerce.

## Capabilities for Maritime Infrastructure

Composites also have game changing potential in water infrastructure and Congress has recognized this potential. At the end of last year, a provision within the Water Infrastructure Improvements for the Nation Act of 2016 directed the US Army Corps of Engineers to study the performance of composites and other innovative materials in water infrastructure projects (such as dams, locks, levees, and more) and make recommendations on their further use.

Because of their anticorrosion properties, composites provide superior performance in wet and high salinity environments. Creative Pultrusions offers a variety of solutions in this sector, as do many other composites manufacturers. Our SuperLoc sheet piling system is one example, designed to rehabilitate deteriorated waterfront structures subjected to harsh marine

environments. Advanced ultraviolet additives protect coastal reinforcements from sunlight and heat degradation and are coupled with composites' proven ability to withstand corrosion and structural degradation in fresh and salt water environments These properties allow for extended service life along with reduced maintenance costs.

Our pipe piling system brings the same property advantages to docks and piers with fender and bearing piles. Unlike wood structures, they are inert to degradation from salt, wood borer, fungi or microbial attack. In addition, they require no external chemical treatment that could ultimately leach and pollute adjacent water sources. A similar product, our fender pile system, was used to rehabilitate the service dock at the Statue of Liberty in the wake of Superstorm Sandy.

## **Breaking Down Barriers**

Noting the performance benefits of composites and the fact that the various composite products discussed here have been used in infrastructure projects for many years, it is fair to ask why they remain such a small fraction of the materials market. The answer is a difficult one. Engineers and asset owners tend to the use of new materials, technologies, and methods of construction, even when it is clear the new technologies offer important advantages. We can appreciate the appeal to an engineer of using tried and true methods and materials when designing and building structures. However, composites have a proven track record of success in a broad field of applications. Congressional and federal agency leadership should not miss an opportunity to encourage engineers, contractors, and governmental asset owners to think differently and critically about the way structures are built in America and to not simply rely on methods and materials of the past.

Standards are another crucial issue. Our industry has made strides in the last few decades toward promulgating design standards and test methods, but a gap remains in the utilization of standards and this fact inhibits greater adoption of composites. The Federal Government has been instrumental in the development of standards for other material industries. Given the potential composites bring, and the significant investments being made by other governments around the world, now is the time for Federal agencies to work with industry to assess the state of standards and work with our industry as we work to standardize many of our applications. The National Institute of Standards and Technology has already begun an effort to make strides in this area, one that Creative Pultrusions and my fellow ACMA members applaud and support.

While in some cases composites can have an increased front end purchase when compared to traditional materials, their extended life and performance means that the lifetime costs can be significantly lower. Further, as demand increases and composites become more regularly used, costs will likely fall.

# Conclusion

America, and frankly the world, is moving into exciting times with respect to innovative materials, such as composites. Traditional materials like wood and steel have dominated the materials marketplace for centuries – arguably back to when wood was used in structures during the Stone Ages. These materials have served us well will continue to hold a prominent role in the materials space going forward. However, as this hearing is focused on disrupters, composites are leading the evolution of materials and are a disruptive force. Composites, through their use of technology and science, have corrosion resistance and lightening properties (to name a few)

that make them attractive in modern applications. In fact, the ability of composites to meet nearly any design challenge makes them highly utilized in high tech and performance driven applications.

These structural characteristics have led to market adoption in broadening fields year in and year out from armoring military vehicles to lightening the cars we use to commute to work. While evolution is always a disruptive force, the advancement of science and technology holds benefits for our society. American composite manufacturers like Creative Pultrusions are at the forefront of this field. Nearly every key development in our industry since its inception was piloted in the United States, but other countries have accelerated research and development and reaped the rewards. This hearing, on disrupters, is an important opportunity to showcase not only the disruptive force of innovation, but should also highlight the need for government to ensure that these disrupters have a framework and an environment to encourage their continued advancement and market adoption. Thank you for the leadership to hold such a hearing and for the invitation to share composite's role as a disrupter in the materials space.

America faces critical challenges. Whether in infrastructure as discussed here, energy, automotive, defense, aerospace, marine or a host of other sectors, Creative Pultrusions and our fellow composites manufacturers represented by the American Composites Manufacturers

Association are ready to provide solutions that work. We all need to look toward solutions that are smarter, more innovative, more sustainable, higher performing and overall better investments. Our safety, stability, and economic prosperity, and that of our children and

grandchildren is at stake. We in the composites are industry are prepared to work with you to provide  $21^{st}$  Century materials for a  $21^{st}$  Century infrastructure.

Mr. LATTA. Well, thank you very much.

And we will now move into our question-answer portion of the hearing, and I will recognize myself for 5 minutes for opening questions.

First, let me just thank you all for being here again, because it is fascinating, especially where you are all taking us is amazing. But I just wrote down a few other questions, if I could just get maybe brief answers to.

Dr. Tour, you had mentioned that you had started three companies recently, and they all started abroad. What countries did you

go to, because of the tax question?

Mr. Tour. They were all started in Israel.

Mr. LATTA. In Israel. Thank you.

Mr. Murphy, if I could ask you a question, you were talking about—because we always have discussions around here about FDA and where we are going and who is faster, European, U.S. And you said that the European and Japanese have been implementing, I believe theirs, it sounds like it is faster than we are doing it here. Would that be correct? Did I understand that?

Mr. Murphy. They have given clarity to the pathway. It is not specifically about how fast in Japan. It has the promise to be fast-

er.

Mr. Latta. Could you maybe define more clarity to that path-

way?

Mr. Murphy. Yes, absolutely. In Europe, they have a dedicated pathway for advanced medicinal therapies that they established a while ago, and it has just been getting use and has more clarity

about how it operates.

21st Century Cures Act in the U.S. actually requires the establishment of an accelerated pathway for tissue and cell-based therapies which we think will be attractive, but it doesn't change the safety mandate. It simply requires speedier review, or it is yet to be seen.

And so what we are asking for today, one thing we would like to see is proper and speedy implementation of what that pathway will be. We need clarity in our industry to keep companies here in the U.S. and keep the clinical trials here in the U.S., because even U.S.-based companies will often go overseas to run their clinical trials first, because they see more clarity in the process.

Mr. LATTA. Thank you.

Dr. Rabiei, I am just kind of curious. Maybe I missed it. How thick is that material? And what is the weight factor, especially in

that protective armor that you are working on?

Ms. Rabiei. We have made armor that all of them were less than an inch. And we have been putting them in front of very large threats, like armor-piercing kind of threats. They call it 7.62, .50 cal. And it performed always surprising. One of my colleagues that I have been working with from Advanced Aviation Research Center, he always tells me when I take samples there, he says, Afsaneh, your samples always surprise me, and I am not surprised anymore, because you have surprised me enough.

So it always performed well. Of course, we don't claim that it is perfect in all different directions. Definitely, we do need support to further develop the material for specific applications. Like, for example, when we put it in front of the blast wave, it is still less than an inch, and it still performed. But how would that work against IED, we still do not know. We put it in front of HEI. So every one of those need more in-depth analysis so that we can take it faster to our soldiers' hands.

Mr. LATTA. Thank you.

Dr. GangaRao, we had hearings and with legislation in the last Congress, especially on pipeline safety. And how would this material work? I know you were explaining about the pressure and all, but would that prolong the life of the pipe by having this technology in that pipe?

Mr. GANGARAO. My colleagues from Creative Pultrusions have been manufacturing these kinds of pipes for a few years. And there are several advantages of this type of a pipe, number one. It is of

higher strength and lower weight.

Number two, it is noncorrosive, and it is nonconductive. And it can take much higher pressures on a sustained basis and be able to enhance the safety, because there will be no burst-type failures for one reason or the other.

Mr. LATTA. Well, thank you.

And, Mr. Weyant, if I could ask you, you mentioned something that caught my ear, that you had a bridge deck that went in in 14 hours?

Mr. WEYANT. Yes.

Mr. LATTA. How big was that deck, just out of curiosity?

Mr. WEYANT. The actual bridge in Wheeling was 200 feet long, and approximately 68 feet wide, with a sidewalk.

Mr. LATTA. In 14 hours?

Mr. WEYANT. That deck was installed in 14 hours. So knowing concrete would be probably a 30- to 40-day just on the deck itself to disrupt the traffic and delays.

Mr. LATTA. Well, I know that they were doing some replacement on I-75 not too far from me, and they slid the bridge in, but it was an all-day affair. And getting everything lined up at 14 hours is quite an accomplishment.

And I have overrun my time, but I really appreciate your testimony today. And at this time, I am going to recognize the

gentlelady from California for 5 minutes.

Ms. MATSUI. Thank you very much, Mr. Chairman. And I agree, this has been absolutely fascinating testimony that we have heard here today. I keep thinking about all the things that we can be doing with some of the products that you are talking about.

But let me just first, I want to ask all of you just quickly, did you receive Federal funding during the process of developing your material and, if so, can you describe for me the role that Federal

funding played? And this is just quickly.

Mr. Tour. Yes. I received a lot of Federal funding for our work on graphene from the Air Force Office of Scientific Research and the Office of Naval Research, and it was critical for the development. Without that, we never could have done this.

Ms. MATSUI. OK. Thank you.

Mr. Murphy. The founding technology which came out of the University of Missouri was funded heavily by the National Science Foundation. After the formation of the company, we have gotten

multiple NIH SBIR grants. And we also benefited from an ARRA grant that was established for biotech companies. We also just got a great score on our latest NIH SBIR grant. So if you guys can pull any strings, that would be great.

Ms. MATSUI. I think I heard, but is there more that you would

like to tell us about your funding?

Ms. Rabiei. Sure. We also have received funding, as I mentioned in my presentation, again, started from National Science Foundation, where discovery began. I absolutely support that statement.

All of the funding that I have received so far were through my university. We have multiple patents and we have started a company to commercialize the technology, and the company has not received any funding.

Ms. MATSUI. OK. Dr. GangaRao?

Mr. GANGARAO. The Constructed Facilities Center at West Virginia University has been receiving funding from the National Science Foundation since the mid 1980s. We have also been getting good bit of funding from the Department of Defense, Army Corps of Engineers, Department of Transportation. And we are very fortunate to have been consistently receiving their support.

We want to emphasize that these composite materials might look a little bit more expensive to begin with in terms of the initial cost. However, there are certain products that we have developed with industry folks like Creative Pultrusions, able to install them at

about half the price of conventional material.

Ms. MATSUI. All right. Thank you.

Mr. WEYANT. Yes, Congresswoman Matsui. We have received Federal funding on the bridges. In early 2000, there was some funding put in place to help offset the cost difference, the original cost difference of the materials. That also was allowed to let us develop other technologies that we could use in other infrastructure areas to develop a lot of our marine structures. So we appreciate that support.

Ms. MATSUI. Thank you.

Dr. Rabiei, you know, in the past few years, this committee has done a lot of work on the issue of head injuries and brain trauma in sports. We often use an analogy to a yolk in an eggshell. Helmets may be able to protect the skull from fractures, but not protect the brain from injuries.

I am curious. Do you see any potential application for your invention in that area? And how would it be different from the traditional helmets?

Ms. Rabiel. Yes. Actually, I was here in D.C. last Wednesday, with a group of people who were advocating for Society for Brain Mapping and Therapeutics. So there were, like, six brain surgeons, and I was the only rocket scientist in there.

So one of the potential applications of the material can be for helmets, and for any kind of protective layers. So what I always say is that when you want to transfer an egg, you put it in Styrofoam. When you are transferring glass, you put it in bubble wrap.

When you transfer humans to outer space, or from here to another place in an airplane, in a train, or send them to hockey or in a war field, you don't protect them. We care more for the glass than for the human. We just put it in a solid material, and what

solid material does is just to transfer the load from one side to the other, and it is not my problem. But when you put it in a porous metal, the porous metal squeeze and the human behind it is protected. So whether it is helmet, whether it is armor, whether it is in front of the car, it works.

Ms. Matsul. Well, that is wonderful.

We also have jurisdiction over automobile safety. How about metal foams, can they be used to reduce the damage of vehicle crashes?

Ms. Rabiei. For, I am sorry?

Ms. Matsul. Metal foams. Is that possible to reduce the damage? Ms. Rabiel. Yes. Yes, absolutely. I had some funding from the DOT, and a program called IDEA that was for crashworthiness and impact protection. So in our preliminary studies, it shows that if you put two pieces of our material in front of the car and have an accident, like 35 miles per hour, it will feel like 5 miles per hour for the passenger sitting in the car, because the energy is absorbed and damped, but—

Ms. MATSUI. Thank you very much. Could I have just one more

question?

Mr. Latta. Yes.

Ms. Matsui. I was curious. I live in Sacramento. We have two big rivers and we are always talking about water infrastructure. So I was curious, because some of what you are talking about might be very helpful for us, if we are thinking about materials that would be stronger and be able to withstand more pressures and things like that.

Are there available—when you build bridges, are you also think-

ing about dams and things like that also?

Mr. GANGARAO. Yes, we have a great bit of funding from the Army Corps of Engineers. And we have recently, about 4 years, 3 years ago, we rehabilitated a dam underwater, without draining it out, using the composite materials.

Ms. MATSUI. Oh, that sounds pretty good. OK. Well, thank you.

I know I have run out of time. Thank you.

Mr. LATTA. Well, thank you very much.

The chair now recognizes the gentleman from Mississippi, the vice chairman of the subcommittee, for 5 minutes.

Mr. HARPER. Thank you, Mr. Chairman.

And thanks to each of you for being here. It is fascinating every time we learn more and more about this. So thank you for your work and your concern.

And, Dr. Tour, your testimony earlier and your remarks and your written testimony, if we were to increase the funding for research at universities and the corporate tax rate were reduced, what impact do you see that having—the concern that you have about the brain drain of research scientists?

Mr. Tour. Right. Well, as far as the corporate tax rate, it was on the advice of our accountants to start our companies overseas, and so that would cease. We very much would rather start it here. It is much easier here because of the knowledge that you don't have to transfer it as far. So that would immediately keep companies here that are going overseas, and then two of them are already on the public markets overseas.

As far as the increase in research funding, we have seen very little increase in research funding over the last 8 years. It has been devastating in the universities and so much so that our-I collaborate with the Chinese, and I put their names on our papers. Why? Because I need access to their equipment. They have better equipment than we have in the United States because we haven't been able to maintain our equipment budgets.

I come from a university that is only 4,000 undergraduates, 4,000 graduates, and we have \$5.5 billion endowment. So we are well endowed. We are hurting on equipment. And so I collaborate with people overseas just to get access to their equipment. So this is going to be a long-term problem for our country that I really care

about if we keep on seeing this.

Our best students are now going home. They would gladly take jobs in the U.S. as professors and do this, but they get huge startup packages in China. They have the 1,000 scholars program, which is more than 1,000 people, but they will start it with multimillion dollar packages as young people. So we are losing them. Mr. HARPER. All right. Well, thanks for your input, and I think

we get the message and appreciate that.

Mr. Weyant, if I may ask, you mentioned a number of industries leveraging fiber-reinforced polymer composites in the U.S. from aerospace, automotive, defense, health care. How has your company had to adjust to new materials entering those industries over the vears?

Mr. WEYANT. Well, the big adjustment is trying to develop standardizations that don't exist for advanced composites. A lot of traditional materials, there are handbooks that exist. Dr. GangaRao can

pull out a steel handbook.

So the big challenge I would challenge and ask for is to help develop those standards. A lot of these companies are very small with restricted budgets, but if the government and universities and industry could develop standards to penetrate so any engineer out of school could pull out a standard and develop around these products, that would be a great return.

Mr. Harper. Great. Great. Thank you.

Dr. GangaRao, how large is the market for composite infrastruc-

ture applications? What do you envision?

Mr. GANGARAO. As I indicated, we are dealing with a \$4.5 trillion market in the infrastructure arena for the next 10 years. If I had to make a guess at it, we can easily capture a trillion-dollar type market in the next 10 years provided we do certain things right, as Shane pointed out, and a few others, and I also put it in my testimony.

Mr. HARPER. OK. Great. Thank you.

And, also, Dr. GangaRao, in your testimony, you discussed, you know, the societal impact of developing advanced composites for infrastructure applications. Can you please explain this in a little more detail, that impact? And is there also a monetary benefit to using advanced composites, and if so, in what ways?

Mr. GANGARAO. Let me start with the monitoring aspect of it. For example, the longevity of a given system can be enhanced using the composite, not necessarily displacing existing conventional materials but hybridizing the conventional materials with the composite. I gave you one such example: Take the case of a bridge deck. I believe we can save the next 10 years several billion

dollars, perhaps up to \$50 billion just on one aspect of that.

Then let me move on to something like the railroad ties where the operational costs are tremendously high today. Herein, if I can increase the life expectancy from 10 years, which is what it is today in the southeast United States, to 40 to 50 years, then I can have a huge savings there. For example, New York City today pays \$2,100 a tie for replacement, even though the tie cost is only \$100 to \$150. \$2,100. Now, if I can break this cycle of once in 20 years to once in 50

years, imagine the amount of moneys we are going to-Mr. HARPER. Well, thank you. And thanks to each of you.

And my time has expired. I yield back.

Mr. Gangarao. Yes. sir. Mr. LATTA. Thank you.

The gentleman's time has expired and has yield backed.

The chair now recognizes the gentleman from Massachusetts for 5 minutes.

Mr. Kennedy. Thank you, Mr. Chairman.

Thank you to our witnesses and for the committee for calling this

To our witnesses, thank you for the work that you do, extraordinarily exciting stuff. The pathway from the basic research to the commercialization to bringing these products to market to helping people is, I think, a critical one for policymakers to understand. How academia plays into that is critical as well. And I want to thank you for making the time to testify today and make sure that your thoughts help guide the committee forward as we try to navigate the policy implications before us.

Dr. Rabiei, just to start with you if I may, your inventions have had an exciting range of possibilities. And I wanted to get a sense as we—I mentioned a little bit about that commercialization process. I wanted to get a sense from you as to what comes next so that more people can have access to the potential benefits of your dis-

coveries.

So how are you planning to commercialize your composite metal foam? And if you are, could you tell us more about what that proc-

ess is like and how you are going about it?

Ms. Rabiei. Well, in a nutshell, we have established a startup; it is an LLC company outside of the university. I do have the opportunity to continue research at the university. So, if I get funding from the university, we can continue promoting the technology and figuring out more properties that can be beneficial.

And from the company side, we are hoping to get through the fundraising process and establish a small production line where we can make prototype samples for different companies. Right now, everywhere I have companies from-large companies are making tanks and Army vehicles to body armors to any kind of industry you can imagine. They have seen how the material is performing, and they want to get their hands on the material.

But I do not have production line. I do have a small laboratoryscale production, and that is where we are right now. If we get funding to have our production line established, even a small production line where we can make little larger samples and smallerscale samples, that would take us to the next step faster.

Mr. KENNEDY. And if you had your choice, where would you plan

to manufacture it?

Ms. Rabiei. Right now, I am in North Carolina. So I do not have any plan to take the production outside the country. I do believe

Mr. Kennedy. How about Massachusetts?

Ms. Rabiei. Oh, my daughter would love that.

Mr. KENNEDY. There we go.

Ms. Rabiei. She was born in Boston, actually. Mr. Kennedy. That is what we are looking for.

Ms. Rabiei. And she always wants to come back to Harvard.

Mr. Kennedy. We have got a couple institutions of higher learning in Massachusetts, well, and a couple in Cambridge, too. MIT, that other school in Cambridge, happens to be one of the recipients of one of the national institutes of manufacturing awards from the U.S. Government under the Obama administration but stood up also with a bipartisan piece of legislation passed 3 years ago now creating the national network of manufacturing institutes all over the country. And the one at MIT is based on advanced fabrics.

So, at the kickoff, about a year or so ago at the announcement, Secretary Ash Carter was in Cambridge and talked about how they were trying to develop fabrics—a T-shirt that could tell you if you were sick, a parachute that could repair itself in the middle of a

The ideas and the applications, obviously, of such products are extraordinary and I think exactly the type of innovation that government and working with academia and industry and business community and entrepreneurs teaming up can lower those barriers of entry, increase the ability of innovators to actually take risk without having such a huge downside if those risks fall short but also making sure we keep that pipeline of funding that goes through that basic research, keeping that pump prime so that we can continue to make the groundbreaking discoveries that years later will lead to that commercialization and those end products.

Well, is that understanding of that process correct? And what ad-

vice would you give us as we try to refine it going forward?

Ms. Rabiel. Well, you said it right to point out everything ends up at the funding. If the funding is available, everybody will move wherever the funding goes, right. So that actually is a smart way to do it in a university when you know where the interest is and you can adjust your research to that, and you are going to be a successful faculty.

So, as far as my research goes, we definitely would love to look for opportunities. And wherever opportunities take us, then we will

be happy to-

Mr. Kennedy. I am over my time. If the chairman would indulge me for 10 more seconds. That national network has actually been successful enough that our Republican Governor is mimicking it at a State-wide level creating State-wide manufacturing partnerships for the next generation of innovation if any of you should be choosing to. It has been a rough weather week, but we have got really good sports teams if any of you are interested in locating north.

Ms. RABIEI. Thank you.

Mr. Latta. Ohio didn't have too bad of one, or two.

Thank you very much. The gentleman's time has expired.

The chair will now recognize the gentleman from West Virginia for 5 minutes.

Mr. GUTHRIE. Thank you, Mr. Chairman.

Dr. GangaRao, when I read your testimony, if I could be paraphrasing a little bit, you are saying that one of the things, the obstacles we have, the barriers that have been put up about our composite construction, is being able to evaluate the durability and the cost savings over time. How would you suggest we do that? Which agency should be funded to do that, or how would we go to rectify that problem?

Mr. GANGARAO. We have been doing some work already in the area of durability, and there is a lot that needs to be done. And some of the agencies that have been funding are the National Science Foundation, the Army Corps of Engineers, the Department

of Transportation. So these are some of the agencies.

Mr. GUTHRIE. Are you suggesting that we put some language in to make sure, as projects go ahead, that they check for that long term?

Mr. Gangarao. That is correct. Mr. GUTHRIE. OK. Thank you.

Let me do—now, Dr. Tour, this subject of graphene is fascinating to me. I have been studying it now for about 3 1A½ years. But I have found here in Washington that almost nobody knows anything about it, is aware of the product.

So I am curious: How would you suggest we make people aware to understand the importance of the development of graphene, and what are some of the commercial applications that we could possibly use in discussions for funding? And, thirdly, what would be the best agency that we could plus-up their account possibly so that we would have money to be able to do more work in graphene?

Mr. Tour. So, as far as getting the word out, I mean, there has been a huge amount of press on graphene. I think the people in Washington have been consumed with other things of late. So that is a distraction area that I am not sure I can speak to.

But as far as the areas, this extends—and even from my own work, it goes from the medical area. We have two drugs: one on traumatic brain injury and stroke—traumatic brain injury being the number one disabler of young adults; stroke being the number one disabler of older adults-that are based on graphene nanoparticles that have transitioned to industries.

We have aircraft coatings based on graphene. We have used oil graphene in the oil and gas industry, and we have used graphene, as I said, for healing of spinal cord. So it is very broad. I don't think it would be wise to give it to just, say, the DOD agencies.

I think that taking the money and spreading it across as you did, quite wisely, as the Congress did, with the National Nanotechnology Initiative, they pushed nanotechnology across all the different agencies and said: Each one of you is responsible for pushing nanotechnology through your different agencies. And so we got the NSF, the NIH, and the Air Force, and the Navy, and the Army all pushing, and so it came out of all of these different sectors because it can influence all of those.

Mr. Guthrie. Where do you see applications that we could more demonstratively convince people that this is a product that we should be advancing?

Mr. Tour. So we have

Mr. GUTHRIE. Other than, I heard you say about—some of that, but give me some other things that perhaps we can load our gun

up a little bit to be able to promote.

Mr. Tour. Right. So, on a day like today, for de-icing leading edges of aircraft or de-icing entire aircrafts by putting a coating of graphene, you use a Joule-heated resistive coating. And what it does is it makes it so that you can easily de-ice aircraft without having to use chemicals—this is just a thermal process—or de-icing power lines. No more ice on power lines. There is no more energy. You can just coat these properly, and the magnetic field from the power line heats this just even a few degrees higher than ambient, and you will get no more ice on the power lines.

So it is very good for de-icing applications, which is something you can talk about with somebody today, and then it can extend into the medical applications. When we are talking about the number one disabler of both older and younger adults, what these par-

ticles can do is really quite amazing.

So, again, there are lots of applications. I can give you tens of pages of press releases on different application areas, even from our own university.

Mr. GUTHRIE. OK. I would like to see that.

Mr. Tour. OK.

Mr. GUTHRIE. I know that it has the potential of being a replacement for silicon wafers in our computers, but there is a band gap

problem with that.

Mr. Tour. Right, there is a band gap problem. So probably what we won't do is replace. Where silicon is good, we will use it in other things. So, for example, for heat release or for touch-screen displays, the problem with graphene is, as you said, the band gap is too small. It is too metallic in nature. But its mobility is so high. Its mobility is 100 to 300 times faster than silicon; that means the rate at which you could do computation.

So we have to think about using it in different ways. And there is actually a team actually at MIT that is thinking about using graphene, not as silicon is used but differently in computing. So, if you would change the computing hardware then you could revert to graphene. What people had tried to do is force graphene into the

silicon box, and that has not worked.

Mr. GUTHRIE. Very good. Thank you.

I yield back.

Mr. LATTA. Thank you very much.

The gentleman yields back.

The chair now recognizes the gentleman from Pennsylvania for minutes.

Mr. Costello. Thank you, Mr. Chairman.

And thank you all for your testimony.

Mr. Murphy, you mentioned over 100,000 Americans are on organ transplant waiting lists—or were in 2015, I think. Only 30,000 of those patients received transplants. Is there a potential for your technology and 3D printed tissue to address the needs of these patients, and if so, how? And when do you think treatments like these could be ready for use in patients?

Mr. Murphy. Thank you for the question, Congressman.

Yes, so we are developing a 3D bioprinted liver tissue for transplant into humans. It is now at the stage of animal trials. We have been testing it in rodents quite successfully. It has already established that we can get it to engraft well, persist for months, that it has metabolic function, that you can measure human proteins that are produced by that liver circulating in the animal.

And we are moving this along a normal development pathway anticipating starting clinical trials as soon as 3 to 4 years from now. We are targeting 2020 to have the clinical trials started for this. We think it can be tremendously impactful for patients because there are so many patients, as you mentioned, on the waiting list, in this case for liver. Many people can't even get on the waiting list. If you are elderly or you have other diseases, you are not even going to be put on that waiting list, and there are no solutions. And basically these folks are down to 10 or 15 percent organ function.

So we are sort of on a staircase, I would say, of how we can help people. With the technology we have available today, we hope to give these folks up to 10 or 20 percent function with a patch rather than a full organ that can bridge them to a full transplant that they can get 1 or 2 years later. We can give them 1 or 2 years additional without one. And then longer term, if the technology is applied broadly and we work with others and bring in more tools and technologies to this, we believe we can make fuller organs over time and do full transplants.

Mr. Costello. You referred to a paper from December in which the authors referred to the value of 3D bioprinted human tissue as reducing the need for animals in chemicals and cosmetic testing. Are you aware of existing or ongoing studies that have shown more accurate outcomes regarding drug and product testing using bioprinted tissues versus animal trial methods?

Mr. MURPHY. Yes, thank you.

The best way to think about what we do is that we have been, as a society, for 50 years or more, dependent on a single paradigm, which is testing cells in a dish and using animals as surrogates for humans. But there is a gap between animals and humans. And essentially, that means we don't know a lot about drugs when we put them into humans.

Those are truly experiments done in humans, those clinical trials, and that is why we go so carefully and so slowly, and that is why you end up with major surprises for drugs, things that are unforeseen.

And liver is a classic example because liver cells on a dish don't perform like the liver fully ever, and they stop performing at all like a liver within 3 to 5 days. So the opportunity we have, the reason bioprinted tissues work is because we put the liver cells—we use three different cell types. We put them with specific architecture into the tissue. So it performs more like a native function.

And to your exact question, we have been able to show over time that first with trovafloxacin, which was a known drug failure, that drug, which was tested for many years before it was put into humans—toxicity was not seen in rats and in liver cells in the dish—we could pick it up in 7 days in our system very clearly because there is basic biological function in our tissue that just doesn't exist in those other models. Humans and animals are different.

And so we have got now a growing set of data that was referred to in the paper you mentioned. And people are relying on the fact that, for example, one of the authors of that paper was also from Merck. We have worked with top 10 Pharma companies like Merck, taken drugs from them in a blinded fashion. They have given us a set of 12 drugs that can sometimes include their own clinical trial failure drugs. And we hit those drugs at a very high rate, meaning we found about 70 percent of the drugs that have gone into clinical trials and failed, we can detect the toxicity of those in our system under a month.

So it is a very powerful advance in the predictive tools, and we expect this to extend into diseases, into study of liver fibrosis and other diseases over time, and many other tissues as well.

Mr. Costello. Dr. GangaRao—did I pronounce that correctly?—my question, and it could apply to any of the applications, but in particular, as it relates to infrastructure, and you hear a lot of talk about an infrastructure bill or public spending in the infrastructure space, and the issue of useful life, return on investment, cost-benefit analysis. And some of these applications obviously or may cost more than the traditional means of doing an infrastructure project. The commercial viability, I think, then becomes a question of when is it worth it based on how much more additional wear and tear and years can we get out of it.

and years can we get out of it.

Big picture, and it doesn't just have to relate to infrastructure, but I use that to illustrate the point to ask the question, are there shortcomings, or are there not shortcomings in the analysis on how much it will cost, what the return on investment is, so that as policymakers we are in a position to say, "Well, we can do that project for \$10, or we can do that project for \$15; but if we do it for \$15, it is going to be twice as value-added to the public benefit because of the materials that we are using and the way that we are designing and building a project"?

And I don't ask that question just of you, I welcome everyone to answer it. But I think that there is something to that. I just don't know if, in addition to the technology and the advancements all of you are making, whether we as policymakers and the public have an appreciation for that analysis so that when we make decisions, we are able to justify spending more.

Mr. Gangarao. As scientists, we have been struggling to answer that question with a degree of accuracy. One of the best ways to do it is we have been building these infrastructures for the last 25 years, and we need to field monitor them today and see how well they are doing. We have certain mechanisms of establishing the remaining life; thus, we should be in a position to establish a decent number in terms of the durability of that product. Once we have that done, then we can translate into a reasonable life expectancy of that product. That is issue number one.

And issue number two, you keep talking about the cost. We need to be talking about, how best can we scale up in terms of low-volume productions to high-volume productions? Once we have these two sorted out, recognizing the fact that certain costs will come down with experience with certain kinds of insights into what we have been doing—so these are the three different factors that need to be looked at to get you a decent projection of how much it is going to cost.

Mr. LATTA. And I thank the gentleman for his questioning. Again, I am sorry that our clocks aren't working here in the hearing room, but if you notice when the lights go on for the witnesses,

that is on the 5-minute. But—

Mr. Costello. I am sorry if I went over.

Mr. LATTA. No problem at all. We have had that problem from the start of the committee hearing. So we appreciate your questions.

The chair now recognizes the gentleman from Oklahoma for 5 minutes.

Mr. Mullin. Thank you so much, Mr. Chairman.

And thank you guys for being here.

I have been reading lately on the use and the application, which seems almost endless on graphene—am I saying that right? Graphene? And what I can't wrap my head around is, why aren't we hearing more about this? I mean, it seems like there are so many possibilities. I read that China is outpacing us in this.

And I am just not sure, from a practical standpoint, from even a military perspective to a construction background, I just can't understand, why are we not pushing this? Is it the barriers that we have created? Is it the lack of investment interest from the public? And I really don't know who wants to take this on. Mr. Tour, if you want to take this on or—

Mr. Tour. So I think certainly those in the field, those working in the field know well about this, of how important this is and the advances that are occurring across many different areas, from biomedicine to structural materials to space and aircraft materials. So it is actually quite broad. There is a huge amount of press on graphene. The nice thing about it is that it is so light and you can make single sheets of it and deal with it in this amazing way.

One of the things that is hurting enormously is the cuts that have come or the lack of any increases in Federal support for research to do these types of things, and that is why I have proposed

having these efforts go forward to increase that.

But it is true that China has 25 percent more patents in the area of graphene than does the U.S. But if you look at the Chinese equipment, it is way ahead of us now. And so what I was telling the committee—

Mr. MULLIN. Equipment in which way? Are you talking about the equipment, the ability to produce it?

Mr. Tour. No, I am talking about the analysis equipment just at the university level.

Mr. Mullin. OK.

Mr. Tour. So I partner with Chinese teams just to get access to their equipment. It is really quite odd that the United States needs to go China to get their analyses done. But if you look at the equipment budgets that have come to universities, they have been cut back enormously in the last 10 years. And so, in order to do the nano analyses, we have to partner with the Chinese in order to do

the analyses, and they get their names on our papers.

And they are far more aggressive in starting out young people. We don't have the infrastructure to be starting out the young people in professorships to do this. We train many Chinese, and they are tremendous in our laboratories. And they would all stay and become professors and work here. But it is very difficult for them to stay, number one, because there is very little money to start up the \$1 million-plus startup packages in the U.S. for young faculty whereas they will get that in an instant in China.

It is the problem of making it tough for them to get their green cards here to work. If they have gotten their Ph.D.s here, I am all for them. They have been extremely vetted by me. They have been extremely vetted by us for the last 5 years. And they would come and participate, they never go to our prisons, and they pay taxes. And they add tremendously to what we are doing. So there are very simple barriers that we could begin to deal with these sort of

things.

Mr. Mullin. What do you see as the most practical application

for graphene?

Mr. Tour. OK. So it is like asking me, which one of my four children do I love the most? It is very hard to do that. It is very hard to say a specific application.

Mr. Mullin. Right now, since Jim is with me, it is him, but it

will change when the next one is with me.

Mr. Tour. I understand. I am the same way. I love them all the most, whoever is with me.

In biological applications, it is extreme. So we have seen solutions for great improvements in traumatic brain injury and stroke using graphene. We have seen the melding of spinal cords—

Mr. Mullin. How is that? What are the advances you have seen?

How is this application being practical there?

Mr. Tour. So this was initially funded by the Department of Defense, the medical command and—because so many of our soldiers were coming back from the Middle East theater and Afghanistan with head injuries. And so what it does is these are rapid antioxidants that sequester the superoxide that usually brings damage to the brain based upon reinfusion of the blood after severing of an artery with a head blow.

And it is the same sort of thing that happens with stroke. There is deficient oxygen to the brain. You bring the patient to the hospital. Corkscrew is used to open up or chemicals are used to open up that clot. Re-profusion of blood, the oxidation problems causes

the damage to the brain.

So I can show you pictures of rats that have had their entire spinal cord completely severed all the way through. We put one drop of a graphene solution and bring that spinal cord together. Within 3 weeks, that rat is running and scores a 19 out of 21 on a mobility scale.

Mr. Mullin. Oh, my goodness.

Mr. Tour. And we can do de-icing. We have important materials applications. We have applications for fluorescent materials,

graphene quantum dots. And a lot of this technology has left the U.S. These companies have gone overseas.

Mr. Mullin. On the spine, have there been any studies on a

human on this?

Mr. Tour. No, no studies on humans. The studies on humans are going to take place certainly overseas because of the lower barriers for that overseas. And those studies may, in fact, take place this

year on humans overseas.

Mr. Mullin. Well, I think you can see that—one, my time, I guess, is out because I saw the red light up there, but you can see this panel and this committee is very intrigued. Moving forward, I would love to be as helpful as I can. Of course, the building composites of it is intriguing, but the human composites of it is extremely intriguing. And I want to be as helpful. You will find my office being helpful, but I think you will find this committee being helpful too. So thank you so much for you all's time.

Mr. LATTA. Well, thank you very much. The gentleman's time has expired.

The chair will now recognize the gentleman from Texas for 5 minutes.

Mr. Burgess. Thank you, Mr. Chairman.

And, Mr. Chairman, being the previous chairman of this subcommittee, I just want to acknowledge that I feel your pain that one of the preeminent technological committees in the United States House of Representatives, the greatest deliberative body in the free world, does not have a clock. It pains me. So I will put my full force behind getting you a new clock.

And I apologize for missing part of the hearing. Obviously, there is a lot of stuff going on with the snow day and just the fact that

there is a lot going on right now.

But, Dr. Tour and Mr. Murphy, perhaps let me direct my ques-

tions to you.

Dr. Tour, I believe you referenced the nanotechnology bill that we did here in 2003 and 2004. I was on the Science Committee at the time but deeply involved with that.

And then, Mr. Murphy, in your written testimony at least, you reference Cures for the 21st Century Act from the last Congress.

So I realize it is a little bit risky, given the answer you gave to Markwayne Mullin from Oklahoma about funding, but can you kind of look over the horizon and perhaps give us some insight? Here we have two major pieces of legislation: nanotechnology, Cures for the 21st Century. What are some other things that you see as worthy of your time and attention?

Mr. Tour. I think, broadly, looking at the funding that was available when I started as a faculty member 30 years ago, the funding available to faculty members on a per-faculty-member basis around the country, and get back to numbers like that. It used to be we would write three proposals in order to get one funded. Now you have to write 10 to get 1 funded, and people are just giving up. They are going overseas. They are leaving the country.

Mr. Burgess. May I interrupt you for a moment?

Mr. Tour. Yes, please.

Mr. Burgess. Is that at the NIH or Department of Defense or all of the aboveMr. Tour. This is across the whole thing. Mr. Burgess. OK. Please proceed.

Mr. Tour. So I think if we looked at what is being put into science and engineering training in the United States and look at the funding rates per professor and begin to move that back up, because we haven't been increasing, and so we have just been killed by the cost of research, and the funding has been flat. So, overall,

we are down more than 40 percent.

Mr. Murphy. So, Congressman, you ask about 21st Century Cures and what to focus on next. Well, there is a lot left open in 21st Century Cures. One of the things it does talk about is a pathway for new drug discovery tools to be validated. One of the things we are focused on is asking you to accelerate the adoption of available tools that are already proven versus focus on longer term investment for things that won't yet be available.

The opportunity with our technology is to-

Mr. Burgess. May I ask you to give us a couple of examples of the current tools that are available?

Mr. Murphy. I would mention one that Organovo has produced, but there are a number of technologies. But, for example, our liver tissue to test safety for drugs for toxicology has a growing set of proof on it and has been published on by the director of the National Center for Toxicology Research and an associate VP of toxi-

cology at Merck as something that is part of the future.

So there is a growing body of evidence around that driving adoption of that. And getting clarity at FDA through this validation of the drug discovery tools that is laid out in 21st Century Curesthere is an opportunity to include that in PDUFA VI as wellwould give clarity to people who want to use that but don't know how the FDA will rely upon it. Giving the FDA the ability and the clear guidance to actually be studying these and issuing guidance around them will be very helpful to achieve the potential of these technologies, which is to lower the cost of drugs.

If you are avoiding these billion-dollar failures for drug toxicity safety issues that are late stage in clinical trials, if people can instead fine tune the drugs with tools that are now available and pick the right ones, you get the avoidance of those costs, the reduction of drug costs overall, and you enable patients to get safer

drugs faster.

Mr. Burgess. I know Dr. DePinho at MD Anderson Hospital has talked about getting to failures quickly so you avoid the time and trouble and expense of a long pathway to something that is ulti-

mately not going to be successful.

Now, Mr. Murphy, you also mentioned—and I guess it is in relation to your liver work—treating some of the inborn areas of metabolism and, of course, the rare diseases that we heard so much about during the Cures hearings, and obviously, those are very sympathetic populations when they come in and talk with us. Is that something that we can actually look to for clinical results in the near future?

Mr. Murphy. That is another indication we are pursuing. So I described the bridge to transplant and liver transplant capabilities of this tissue patch. The liver tissue patch would also be used for inborn areas of metabolisms. So an example of that would be something like hemophilia, where people lack the factor for blood clotting. The genetic deficiency expresses itself in the liver where those

factors aren't produced.

But there is alpha-1 antitrypsin deficiency and a number of others, and by giving a patch, we think we can supplement the production of that or create the production of that key factor inside a patient who suffers from inborn areas of metabolism, yes.

And that will be on the same timeframe: 3 years to clinical trials. And it would help us if you could, in the implementation of 21st Century Cures, assure the accelerated pathway for tissues is clear for folks like us when we bring those to the clinical trial stage.

Mr. Burgess. Very good.

And, Dr. Tour, I would just be remiss if I did not echo what Markwayne Mullin from Oklahoma said: if you have got a way take your hexamethyl chicken wire and help people walk again with spinal injuries, we want to help you.

So thank you, and thank you all for your testimony today.

I yield back.

Mr. LATTA. Well, thank you.

The gentlelady from Illinois formally passes at this time.

The chair will recognize the gentleman from Florida for 5 min-

Mr. BILIRAKIS. Thank you so very much. I appreciate it, Mr.

Chairman, and I apologize for being late.

Mr. Murphy, I understand your technology holds a promise to lower the cost of drug development. Can you explain to the committee how the use of bioprinted tissues will improve the drug development process and ultimately lower cost for patients?

Mr. Murphy. Yes. Thank you for the question, Congressman.

So what we do is create a tissue that can be used in a number of ways. I have mentioned liver toxicity safety as an example, but patients are suffering right now because we don't have solution's for liver fibrosis. There are animal models for fibrosis that have basically been rejected by Pharma because they are not predictive.

So we have done and Pharma companies have taken forward a number of drugs into clinical trials to try and treat fibrosis only to find out that what was predicted as potentially useful in the animal models doesn't pan out. That is a cost that they build into their overall infrastructure, and we are paying for that cost

through drugs that do get approved.

And if you think about it, it is about avoiding these costly failures and getting to the drugs that will work faster. That is the overall promise. That same liver tissue we use when exposed to known agents that cause fibrosis, like methotrexate—and this is published with the University of North Carolina researchers—induces fibrosis in a way that is clinically relevant and shows a good comparison to what you see in a biopsy of those patients.

So, taking that drug into nonalcoholic steatohepatitis and these fatty liver disease fibrosis things, diseases where Pharma is very focused now gives the opportunity to actually find drugs for those and avoid taking drugs forward that are based only on animal

models and end up having failures.

Mr. BILIRAKIS. Very good. We are here to help as well. I appre-

ciate the panel's testimony.

And I yield back, Mr. Chairman. Mr. LATTA. Well, thank you very much.

The gentleman yields back.

And the chair recognizes the ranking member of the sub-

committee, the gentlelady from Illinois, for 5 minutes.

Ms. Schakowsky. I can't tell you how disappointed I am. My plane was 3 hours late, and I am really, really interested in this panel. I am glad that at least you are here for a few more minutes, and I will look over the testimony in the transcript.

I am concerned about the money that is available for research and want to be sure that we have that. Federal funding contributed directly to American business by ensuring that they can compete successfully around the world is so important. Further cuts in funding for education, government support for small business and research I think would definitely harm our economy and hamper our ability to innovate.

And even worse, these proposed cuts are coming at a critical time as other countries are aggressively ramping up their spending on R&D and education. The U.S. is still the world leader when it comes to government research funding, but at our current levels,

China is projected to overtake us in just a few years.

I think we stand at a moment where the United States of America can be the exporter of such exciting technologies if we actually put the research in. I have the Northwestern University, University of Illinois, University of Chicago that are looking, doing incredible research for improved and nanotechnology at the university, at Northwestern University, batteries at the University of Illinois, just amazing work.

So I want to ask you—and maybe you answered this already, I would like to put it on the record again if you have anyway: how would a further decline in research funding to American univer-

sities affect your work? Anybody.

Mr. Tour. It is already affecting us so that we have not seen an increase in several years. It is already affecting us. If we are going to go down even more, it is going to be devastating to the research science community within the United States.

Our best and brightest are already leaving the country, going back to their home countries because there are no startup packages for their positions here. And China is paying them extremely well. Singapore is paying them extremely well to start up their companies.

And it is not just that. It is our established senior U.S. professors that are now leaving and packing up their programs and going overseas because it is so hard to get funding here in this environment that they can go overseas and get their programs funded.

Ms. Schakowsky. Let me ask you one other thing. I understand too for research, start, and stop is very devastating, that there has to be a sense of continuum here. Is that a problem as well?

Mr. Tour. That is a problem because once it stops, it is very hard to restart, because your students go onto other things; they graduate. That is it; the infrastructure is lost. And so it is very hard to start and re-stop. There is only stop.

Ms. Schakowsky. Thank you.

Anyone else?

Mr. GANGARAO. Dr. Tour is talking about how it affects the students' funding for the faculty, what have you. I would like to take that one step further in the sense that we have exported out our manufacturing industry, and we are hurting very badly now. Likewise, if we begin to export out our research capabilities 10, 20 years from now, you can be assured we will be looking to be a Third World country.

Ms. Schakowsky. Wow.

Yes, Dr. Rabiei.

Ms. Rabiel. I also wanted to elaborate that right now the research environment is becoming harder and harder for us to keep up. I had some colleagues from Europe coming to visit us, and we had a meeting starting from 8 o'clock to 7 p.m., and he was saying, why do you have this kind of long hours? And I said, because, like what Dr. Tour was mentioning, we have to write 10 proposals if you want to get 1.

So if you want to have 5 proposals funded, then you have to write 50 proposals, and each one of them take a lot of time if you want to write something competitive. On top of that, you have teaching and you have other service and writing and supporting Ph.D. students and all that.

So it is really competitive, and the more you cut the budget for research, the more it becomes competitive because we still have to compete for that, and our chances go down. Like, if you look at NSF reports, they say it is 1 out of 13 that is funded. Sometimes it is 1 out of 10 is funded. So, obviously, in all of this, people write 100 proposals; 90 of them are down into trash, and 10 of them are funded.

Ms. Schakowsky. Does the funding also shape the research you do? Because if you know that funding is available, you may go in a different direction? I think that could be a not-great thing.

Mr. Tour. It is not a great thing. You are always chasing money.

Ms. Rabiei. Yes.

Mr. Murphy. Mr. Chairman, can I add a comment to the question?

Mr. LATTA. Go right ahead.

Mr. Murphy. Out-of-the-box thinking, we are supposed to be disruptive. After my success in founding the company, I started with my own money a nonprofit that gives philanthropic dollars in terms of research grants. So Jason Wertheim, who is a surgeon at Northwestern, transplant surgeon that does research on de novo organs, received a grant from Human Organ Project that is non-profit.

If there were ways that Congress could—there is not a lot of that kind of funding that—private, philanthropic funding that goes directly into research grants. There is a lot of work that is done for

patient education, patient help, and things like that.

If there were ways over the long haul—I don't have proposals in mind; this is just coming to me—if there were ways that Congress could work toward stimulating more philanthropic investment direct in the research grants, some of which, honestly—you know, a lot of stuff goes overseas in terms of world health and things like that, very noble enterprises. But if there were ways to get more di-

rect private investment into research in the U.S., that would be helpful too, I think.

Ms. Schakowsky. Let me just say: I agree with you, but on the other hand, I don't think private dollars are going to be able to make up the difference between an investment by the Federal Government. But it is still a good thing.

Mr. Latta. Well, thank you very much for our panel today. You can tell from the questions you received from the subcommittee that we are all very, very interested in this, and we really appreciate your testimony and your expertise and being with us today. And in pursuant to committee rules, I remind members that they

And in pursuant to committee rules, I remind members that they have 10 business days to submit additional questions for the record. And I ask the witnesses to submit any responses within 10 days upon request or other questions.

And, without objection, the subcommittee will stand adjourned.

Thank you very much for coming.

[Whereupon, at 1:53 p.m., the subcommittee was adjourned.]

 $\bigcirc$